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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: DIRECT PURCHASER INSULIN PRICING LITIGATION	)	Case No. 3:20-cv-3426 (BRM)(LHG)
This Document Relates To:	)	<b><u>FIRST AMENDED CLASS ACTION COMPLAINT</u></b>
All Actions	)	Demand for Jury Trial

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FWK Holdings, LLC (“FWK”) and Professional Drug Company, Inc. (“PDC”) (collectively, “Plaintiffs”), individually and on behalf of all others similarly situated, allege the following based upon personal knowledge as to Plaintiffs, the investigation of counsel, and information and belief. Plaintiffs believe that substantial evidentiary support exists for the allegations set forth herein.

## **I. Summary of the Case**

1. Defendants herein are the drug companies Eli Lilly and Company (“Eli Lilly”), Novo Nordisk Inc. (“Novo”) and Sanofi-Aventis U.S. LLC (“Sanofi”) (together, the “Manufacturer Defendants”), and pharmacy benefit managers (“PBMs”) CVS Health Corporation, CaremarkPCS Health, LLC, Caremark LLC, Caremark Rx LLC, Express Scripts Holding Company, Express Scripts, Inc., Medco Health Solutions, Inc., UnitedHealth Group Inc., United Healthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. (together, the “PBM Defendants”).<sup>1</sup>

2. Plaintiffs bring this class action to recover for the injuries caused by Defendants’ unlawful practices in connection with the marketing, pricing, sale and distribution of the long-acting analog insulins, Lantus® (“Lantus”) and Levemir®

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<sup>1</sup> The PBM Defendants and Manufacturer Defendants are jointly referred to herein as “Defendants.”

(“Levemir”) and the rapid-acting analog insulins, NovoLog® (“NovoLog”) and Humalog® (“Humalog”) that began in 2009 and have continued thereafter. NovoLog, Humalog, Lantus and Levemir are collectively referred to herein as the “Insulin Drugs.”

3. *First*, the PBM Defendants solicited and the Manufacturer Defendants paid bribes and kickbacks not for services rendered, but to induce the PBMs to include the Insulin Drugs on health benefit providers’ “formularies” controlled by the PBMs – formularies that determine whether and to what extent the nation’s health benefit providers pay for their insureds to receive life sustaining insulins – in violation of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c).

4. *Second*, in order to pay for these kickbacks, Defendants contracted, combined or conspired to fix, maintain and stabilize the price of the Insulin Drugs at supra-competitive levels in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

5. *Third*, Defendants operated an enterprise that secured the sale of the Insulin Drugs at artificially inflated prices through a pattern of racketeering activity. Such unlawful conduct included, among other things: publishing artificially increased prices and systematically making false representations through the U.S. mail and interstate wires that the operation of the formulary system (controlled by the PBM Defendants) and the pricing mechanism for the

Insulin Drugs used by the Manufacturer Defendants operated to reduce the cost of analog insulin to purchasers. In reality, however, Defendants were systematically acting to increase prices of the Insulin Drugs by engaging in kickback and price-fixing schemes – in violation of the provisions of the Racketeer Influenced and Corrupt Organization Act (“RICO”), 18 U.S.C. §§ 1962(c) & (d).

## **II. Jurisdiction and Venue**

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337(a), Section 1 of the Sherman Act, 15 U.S.C. § 1, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26.

7. This District Court is already adjudicating parallel class action litigation commenced by consumers who have sued certain defendants for perpetrating their unlawful scheme to inflate analog insulin prices. *See In re Insulin Pricing Litig.*, No. 17-699 (D.N.J.).

8. From January 1, 2009 to the present (the “Class Period”), Defendants sold and shipped the Insulin Drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of the Insulin Drugs in this District and throughout the United States. Defendants’ conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the U.S., including in this District.

9. Throughout the Class Period, Defendants also perpetrated their pattern of racketeering activity through their use of the U.S. Mail, as well as interstate and international wires.

10. This Court has personal jurisdiction over each Defendant because, *inter alia*: (a) Defendants maintain their principal places of business in this District; (b) Defendants transacted business throughout the U.S., including in this District; (c) Defendants participated in the selling and distribution of the Insulin Drugs throughout the U.S., including in this District; (d) Defendants had and maintained substantial contacts with the U.S., including in this District; (e) Defendants were engaged in an unlawful conspiracy and were members of unlawful enterprises designed to artificially inflate the prices for the Insulin Drugs; and/or (f) those conspiracies and enterprises were directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the U.S., including in this District.

11. Venue is proper in this District pursuant to 18 U.S.C. § 1965, 15 U.S.C. §§ 15 and 22 and 28 U.S.C. §§ 1391(b) and (c) because during the Class Period Defendants: (a) resided in this District; (b) transacted business in the U.S., including in this District; (c) were found in this District; and/or (d) maintained agents in this District.

### **III. The Parties**

#### **A. Plaintiffs**

12. Plaintiff FWK is an Illinois limited liability company with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of antitrust and other claims of Frank W. Kerr Co.

13. Based on information currently available, during the Class Period, FWK purchased approximately: (i) \$113,143,774.13 of Lantus directly from Defendant Sanofi, (ii) \$25,455,136.10 of Levemir and \$64,418,385.92 of Novolog directly from Defendant Novo, and (iii) \$45,419,536.95 of Humalog directly from Defendant Eli Lilly.

14. Professional Drug Company, Inc. is a Mississippi corporation with its principal place of business located at 186 Bohn Street, Biloxi, Mississippi.

15. Based on information currently available, during the Class Period, PDC purchased Lantus directly from Defendant Sanofi and purchased Levemir directly from Defendant Novo.

16. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs paid artificially inflated prices for the Insulin Drugs that they purchased directly from the Manufacturer Defendants.

#### **B. Defendants**

17. Defendant Novo is a Delaware corporation with its principal place of business located at 800 Scudders Mill Road, Plainsboro, New Jersey. Novo is one

of the largest producers of insulin drugs in the U.S. During the Class Period, Novo manufactured and sold NovoLog and Levemir, among other insulin drugs, to purchasers in this District and throughout the U.S.

18. Defendant Eli Lilly is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana. During the Class Period, Eli Lilly manufactured and sold Humalog to purchasers in this District and throughout the U.S.

19. Defendant Sanofi is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey. During the Class Period, Sanofi manufactured and sold Lantus to purchasers in this District and throughout the U.S.

20. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island. CVS Health is a PBM and, as such, contracts on behalf of health benefit providers with Novo, Eli Lilly, and Sanofi for purchase of the analog insulin medications these drug companies make.

21. Defendant CaremarkPCS Health, LLC, a Delaware limited liability corporation, formerly known as Caremark PCS Health, L.P., was incorporated in 2002 and is headquartered at 750 West John Carpenter Freeway, Irving, Texas. CaremarkPCS Health, LLC, d/b/a CVS Caremark, provides pharmacy benefit

management services to various health benefit providers. CaremarkPCS Health, LLC is a wholly owned subsidiary of CVS Health Corporation.

22. Defendant Caremark, LLC is a California limited liability company, with its principal place of business located at 2211 Sanders Road, Northbrook, Illinois. Caremark, LLC offers pharmacy benefit management services to various health benefit providers. Caremark, LLC is a wholly owned subsidiary of CVS Health Corporation.

23. Defendant Caremark Rx, LLC is a Delaware limited liability company with its principal place of business located at 211 Commerce Street, Nashville, Tennessee. Caremark Rx, LLC provides pharmacy benefit management services. Caremark Rx, LLC is a wholly owned subsidiary of CVS Health Corporation. Caremark Rx, LLC is the parent of Defendant CVS Health Corporation's pharmacy services subsidiaries and is the immediate or indirect parent of many pharmacy benefit management subsidiaries, including Defendant CaremarkPCS Health, LLC.

24. Defendants CaremarkPCS Health, LLC and Caremark LLC are agents and/or alter egos of Defendant Caremark Rx, LLC. Defendant Caremark Rx, LLC is an agent and/or alter ego of Defendant CVS Health Corporation. For example, Jonathan C. Roberts, CEO of Caremark Rx, LLC, is Executive Vice President and Chief Operating Officer of CVS Health Corporation. Thomas S. Moffatt, Secretary

of Caremark Rx, LLC and Caremark, LLC, is a Vice President, Assistant Secretary, and Assistant General Counsel at CVS Health Corporation. Anne E. Klis, CEO of Caremark, LLC, is Vice President of Professional Practice and Training at CVS Health Corporation. Daniel P. Davison, CEO of CaremarkPCS Health, LLC, is Senior Vice President of Finance at CVS Health Corporation. Melanie K. Luker, Assistant Secretary of CaremarkPCS Health, LLC, is Manager of Corporate Services at CVS Health Corporation.

25. For purposes of clarity, Plaintiffs herein collectively refer to CVS Health Corporation, CaremarkPCS Health, LLC, Caremark LLC, and Caremark Rx LLC as “CVS.”

26. Defendant Express Scripts Holding Company is a Delaware corporation with its principal place of business located at 1 Express Way, St. Louis, Missouri.

27. Defendant Express Scripts, Inc. is a Delaware corporation with its principal place of business located at 1 Express Way, St. Louis, Missouri. Express Scripts, Inc. is a PBM and, as such, contracts on behalf of health benefit providers with Novo, Eli Lilly, and Sanofi for purchase of the analog insulin mediations these drug companies make. Defendant Express Scripts, Inc. is a subsidiary of Defendant Express Scripts Holding Company.

28. Defendant Medco Health Solutions, Inc. is a Delaware corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey. Medco Health Solutions, Inc. is a subsidiary of Express Scripts Holding Company. Medco Health Solutions, Inc. is a PBM and provides pharmacy benefit management services to various health benefit providers.

29. Medco Health Solutions, Inc. and Express Scripts, Inc. are agents and/or alter egos of Express Scripts Holding Company. For example, David Queller, President of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Senior Vice President of Sales & Account Management at Express Scripts Holding Company. Christine Houston, a Vice President at both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Executive Vice President and Chief Operations Officer at Express Scripts Holding Company. John Milmiltz, a Vice President at both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Vice President of Tax at Express Scripts Holding Company. Timothy Smith, a Vice President and Treasurer of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Corporate Treasurer and Vice President of Finance and Indirect Procurement at Express Scripts Holding Company. Rod Fahs, the Assistant Secretary of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Assistant General Counsel at Express Scripts Holding Company. Christopher McGinnis was a Vice President at Express Scripts, Inc., and also a

Vice President and Chief Accounting Officer of Express Scripts Holding Company. Martin Akins, the only member of the Board of Directors of Express Scripts, Inc. and the only member of the Board of Directors of Medco Health Solutions, Inc., and Secretary of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Senior Vice President, General Counsel, and Corporate Secretary of Express Scripts Holding Company. All of the officers of Medco Health Solutions, Inc. are also officers of Express Scripts, Inc.

30. For purposes of clarity, Plaintiffs herein collectively refer to Express Scripts Holding Company, Express Scripts, Inc., and Medco Health Solutions, Inc. as "Express Scripts."

31. Defendant UnitedHealth Group, Inc. is a Delaware corporation with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota. UnitedHealth Group, Inc. is a diversified managed healthcare company. UnitedHealth Group, Inc. offers products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

32. Defendant United Healthcare Services, Inc. is a Minnesota corporation with its principal place of business located at 9700 Health Care Lane, Minnetonka, Minnesota. UnitedHealthcare Services, Inc. is a subsidiary of UnitedHealth Group, Inc. and provides pharmacy benefit management services

through its subsidiaries to various health benefit providers. According to Exhibit 21.1 to UnitedHealth Group, Inc.'s 2016 Securities and Exchange Commission Form 10-K, UnitedHealthcare Services, Inc. also does business as Optum, Inc.

33. Defendant Optum, Inc. is a Delaware corporation with its principal place of business located at 11000 Optum Circle, Eden Prairie, Minnesota. Optum, Inc. is a PBM and subsidiary of UnitedHealthcare Services, Inc., which provides pharmacy benefit management services through its subsidiaries to various health benefit providers on behalf of more than 65 million plan participants.

34. Defendant OptumRx Holdings, LLC, is a Delaware limited liability corporation with its principal place of business located at 2300 Main Street, Irvine, California. OptumRx Holdings, LLC is a PBM and a subsidiary of Optum, Inc. OptumRx Holdings, LLC provides pharmacy benefit management services through its subsidiaries to various health benefit providers.

35. Defendant OptumRx, Inc. is a California corporation with its principal place of business located at 2300 Main Street, Irvine, California. OptumRx is a PBM and, as such, contracts on behalf of health benefit providers with Novo, Eli Lilly, and Sanofi for purchases of the analog insulin medications these drug companies make.

36. For purposes of clarity, Plaintiffs here collectively refer to UnitedHealth Group, Inc., United Healthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. as “Optum.”

37. Defendants have engaged in the conduct alleged in this Complaint, and/or the Defendants’ officers, agents, employees or representatives have engaged in the alleged conduct while actively involved in the management of Defendants’ business and affairs and acting within the scope of their employment.

38. Upon information and belief, various other companies and individuals, not named as defendants in this Complaint, may have participated as co-conspirators in the violations alleged herein, and aided, abetted, performed acts, and made statements in furtherance of such conspiracy.

39. The true names and capacities, whether individual, corporate, associate or representative is unknown to Plaintiffs at this time. Plaintiffs may amend this Complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.

40. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered, or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

#### **IV. Factual Background**

##### **A. The Prevalence of Diabetes in the U.S.**

41. Diabetes is an increasingly common disease in the U.S. that occurs in patients who have a lack of insulin production or an inability to respond to insulin.

42. Insulin, which regulates metabolic processes in the body, is created by the pancreas. Insulin enables cells in the body to absorb glucose from the blood. Glucose serves as energy for cells or is converted to fat for storage. Insulin also regulates the breakdown of fat and protein.

43. The vast majority of individuals suffering from diabetes have either Type 1 or Type 2 diabetes. As of 2020, more than 34 million people in the U.S. had Type 1 or Type 2 diabetes.<sup>2</sup>

##### **B. The Development and Importance of Analog Insulins.**

44. The primary goal in the treatment of diabetes is the management of the patient's heightened blood sugar level. A necessary treatment for Type 1 diabetes and a common treatment for Type 2 diabetes is insulin therapy.

45. Analog insulin is a sub-group of human insulin. It is laboratory grown, but genetically altered to create either a more rapid-acting or more uniformly acting

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<sup>2</sup> See National Diabetes Statistics Report 2020, p. 2, [www.cdc.gov/https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf](http://www.cdc.gov/https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf)

form of insulin. Analog insulin dominates the insulin markets for both long-acting analog insulins and rapid-acting analog insulins.

46. Doctors and patients prefer analog insulins because they more closely mimic the way the human body naturally absorbs insulin released by the pancreas. As a result, analog insulins provide increased treatment options.

47. The American Diabetes Association (the “ADA”) publishes standards of medical care in diabetes.<sup>3</sup> The ADA recommends insulin analogs for both Type 1 and Type 2 diabetes patients.

48. Due to the advantages of analog insulin, sales of natural human insulin products, such as Novo’s Novolin and Eli Lilly’s Humulin, have dropped drastically.

49. IMS data<sup>4</sup> for 2016 shows that the top-selling insulins in the U.S. were analogs: Lantus (\$8.87 billion); Levemir (\$1.82 billion); NovoLog (\$5.86 billion); and Humalog (\$5.88 billion).

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<sup>3</sup> See American Diabetes Association Standards of Medical Care in Diabetes – 2017, THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION, DIABETES CARE®, [http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement\\_1.DC1/DC\\_40\\_S1\\_final.pdf](http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf).

<sup>4</sup> IMS data is provided by IMS Health, Inc. (“IMS Health”) (n/k/a IQVIA). IMS Health collects pricing data from retail pharmacies, including independents, chains, and pharmacies within food stores or mass merchandisers,

**C. Analog Insulin Brands are Therapeutically Interchangeable.**

50. The long-acting analog insulins Lantus and Levemir are very similar drugs with few differences that impact treatment. They are generally considered to be therapeutically interchangeable.

51. Both Lantus and Levemir are available in vial and cartridge delivery forms and are suitable for once-daily administration.

52. Likewise, the rapid-acting insulins NovoLog and Humalog appear to have identical effects in diabetes patients. Thus, NovoLog and Humalog also are considered therapeutically interchangeable.

53. Studies show that there is no meaningful difference in the effectiveness of Levemir versus Lantus, or Humalog versus NovoLog. The FDA has stated that, in certain circumstances, one brand of rapid-acting insulin may be substituted for another brand of rapid-acting insulin and that one brand of long-acting insulin may be substituted for another brand of long-acting insulin.<sup>5</sup>

54. Generally, diabetes patients can easily switch insulin brands. In most states, a physician does not need to write a new prescription for a patient to switch insulin brands.

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<sup>5</sup> See “Information Regarding Insulin Storage and Switching Between Products in an Emergency,” <https://www.fda.gov/drugs/emergencypreparedness/ucm085213.htm>.

**D. The Participants in the Distribution and Sale of Pharmaceuticals.**

55. The critical players in the prescription drug industry include drug companies (*i.e.*, manufacturers), direct purchasers (usually wholesalers like Plaintiffs), pharmacies, health benefit providers (such as institutional insurers, self-insured employers, and health and welfare plans), PBMs, and patient-consumers.

56. **Drug Companies.** Drug companies, as referred to as manufacturers, own the rights to manufacture and market drugs. Drug companies typically own or contract with facilities that manufacture drugs and then sell their products to distributors, (*e.g.*, Plaintiffs) and other direct purchasers, such as certain large retail pharmacy chains.

57. **Direct Purchasers.** After production, drug companies sell their drugs to direct purchasers such as FDA-registered drug distributors— like Plaintiffs— and certain retail pharmacy outlets. The price paid by the direct purchasers to purchase a drug is set by the drug company. Here, the ultimate price paid by Plaintiffs and Class members for the Insulin Drugs (“Direct Purchaser Prices”) was, and is, tied, or tethered, to what is referred to in the industry as the “Wholesale Acquisition Cost” or “WAC.”

58. Here, Manufacturer Defendants typically send Plaintiffs and Class members notifications regarding new Direct Purchaser Prices via the U.S. mail, electronic mail or interstate wires.

59. **Health benefit providers.** Institutional insurers, self-insured employers, and/or health and welfare plans are collectively referred to herein as “Health benefit providers.” Health benefit providers submit payments on behalf of insured individuals to healthcare providers (doctors and medical facilities) for services rendered to the covered individuals. Health benefit providers also cover a portion of their beneficiaries’ drugs costs, submitting payments to pharmacies on behalf of their members.

60. **Pharmacy Benefit Managers.** PBMs effectuate financial and contractual arrangements between and among drug companies, pharmacies, and health benefit providers. PBMs can perform a variety of services on behalf of their health benefit provider clients, including negotiating prices with drug companies, creating and managing formularies, managing prescription billing, constructing retail pharmacy networks for insurers, and providing mail-order services.

#### **E. The Power of the PBMs.**

61. PBMs have expanded from pharmacy claims processing to a business model that forces drug companies to engage in price negotiation in several drug categories. PBMs typically select one brand among several brand drugs in a therapeutic class as the “preferred” choice and then negotiate payments from that manufacturer called “rebates.” So long as those rebates are passed back to the

client, this rebate system could lower the net cost of that brand to health benefit providers.<sup>6</sup>

62. PBMs generally are not a direct link in the physical supply chain for pharmaceutical products. In most instances, PBMs do not take possession or control of prescription drugs.

63. PBMs bring in more than \$200 billion a year in revenue. Because increased size gives an individual PBM increased negotiating leverage there has been dramatic consolidation in the PBM industry during the past decade. By 2014, the top three PBMs (the PBM Defendants) controlled over 80% of the PBM market, covering 180 million insured people.<sup>7</sup>

64. According to a May 2019 industry article, at the end of 2018, the PBM Defendants continued to control over 75% of the covered lives.<sup>8</sup>

65. In contrast, the market for health plans and insurers is less concentrated, with the 25 largest companies accounting for less than two-thirds of the market in 2014.<sup>9</sup> For brand name drug companies, 13 companies account for

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<sup>6</sup> Health Affairs, “Prescription Drug Pricing: Pharmacy Benefit Managers,” Health Policy Brief Series (Sept. 2017) at p. 1.

<sup>7</sup> *Id.* at 2.

<sup>8</sup> “CVS, Express Scripts, and the Evolution of the PBM Business Model,” Drug Channels (May 29, 2019), <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html>.

<sup>9</sup> Evi Heilbrunn, “Top Health Insurance Companies,” U.S. NEWS & WORLD REPORT (Nov. 5, 2014), <https://health.usnews.com/health-news/health->

90% of the U.S. market.<sup>10</sup> Thus, it is typical to have a large PBM negotiating with several drug companies on behalf of a large number of relatively small health benefit providers.

66. One of the key functions that PBMs perform for their clients is to negotiate supposed “rebates” with drug companies. However, rather than negotiating agreements with drug companies separately and individually for each of their health benefit provider clients, PBMs typically use their combined clout to negotiate a master agreement on behalf of all their clients. As a result, in the world of drug price negotiation, market power is most highly concentrated among PBMs, and in particular the PBM Defendants, who have more negotiating leverage than any individual drug manufacturer or health benefit provider on either side of a transaction.

67. Because the PBM Defendants can negotiate better deals than health benefit providers can get on their own, they are in a strong position when negotiating contract terms and conditions with the health benefit providers they represent. While a PBM is nominally “hired by” and “working for” a particular

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insurance/articles/2013/12/16/top-health-insurance-companies; Charles Roehrig, “The Impact of Prescription Drug Rebates on Health Plans and Consumers”, Altarum (Apr. 2018) at p. 8, <https://altarum.org/publications/impact-prescription-drug-rebates-health-plans-and-consumers>.

<sup>10</sup> *Id.*

client, the PBM Defendants are actually in the driver's seat. While health benefit providers may technically have the right to independently control rebate negotiations, they have delegated that power to the PBM Defendants.

#### **F. PBMs Control Drug Formularies**

68. Formularies are a central tool that health benefit providers use in designating, managing, and publicly identifying the extent of the coverage and benefits they provide to their members. Because formulary coverage impacts how much a patient pays for a drug, formularies can be used to steer patients toward certain drugs over others, and that is one of the key purposes and functions of formulary design, implementation, and management.

69. While some PBM clients have formal, nominal control over the structure of the formularies they implement, they usually retain the PBMs to administer the formularies and give the PBM contractual authority to make day-to-day changes, unless the health benefit provider takes the affirmative step of electing not to implement any such change. Here, the PBM Defendants have contractual authority to make day-to- day changes.<sup>11</sup>

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<sup>11</sup> Sample Form of PBM Agreement with Express Scripts, Inc., Genessee County (Flint, Michigan) Purchasing Department (Feb. 27, 2015), <https://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage-2.pdf>.

70. Most health benefit providers rely upon a PBM's formulary recommendations.<sup>12</sup> Indeed, the Express Scripts contract template provides that Express Scripts' additions and/or deletions to the formulary are automatically assumed to be adopted by the health plan sponsor, unless the sponsor takes the affirmative step of electing not to implement any such addition or deletion through the set-up form process.<sup>13</sup>

71. The PBM Defendants' contractual authority to make changes to the formulary list, combined with many clients' reliance on the PBM Defendants' formulary recommendations and decisions, gives the PBM Defendants substantial day-to-day control in managing their clients' formularies.

72. The PBM Defendants' control over formulary decisions is related to (and a necessary predicate of) their ability to negotiate manufacturer rebates, because manufacturers pay rebates based on the PBM Defendants' ability to deliver formulary placement for their drugs. This is because favorable formulary

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<sup>12</sup> The PCMA — the PBM trade association — has testified to the Pennsylvania House of Representatives that even sophisticated health benefit providers, *i.e.*, insurers and health plans, rely on PBMs to manage their drug benefit. Letter from PCMA to the Matthew E. Barker, Pennsylvania House of Representatives, House Comm. on Health (Aug. 28, 2013).

<sup>13</sup> A well-known pharmacy-benefits consultant, David Dross, noted during a presentation that health plans “don’t have clinicians on staff, they don’t even question their PBM’s formulary, much less design their own.” *Employers Should ‘Ask the Hard Questions’ About PBM Formularies*, Health Business Daily (Dec. 19, 2014), <https://www.coleridgelaw.com/archive/nhpw120814-03>.

status is likely to increase (or at least maintain) a drug’s usage and sales and formulary exclusion (or a downgrade in formulary position) is likely to reduce a drug’s usage and sales. Manufacturer rebates are conditioned on a drug’s formulary coverage.<sup>14</sup>

73. In the past, PBMs generally devised and managed what are known as “open” formularies: formularies that offer varying degrees of plan coverage and benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies compete to have their drugs placed by PBMs into the most favorable formulary tier possible.

74. Like open formularies, “closed” formularies provide tiered benefits, but unlike open formularies, they restrict the overall number of drugs that are entitled to receive any plan prescription drug benefit.

75. In the 2010s, PBMs, including the PBM Defendants, started shifting to making “closed” formularies the default choice for clients.<sup>15</sup> For example, in

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<sup>14</sup> As Cottingham & Butler (a national insurance broker) noted in a client presentation, PBMs have “unilateral control . . . over formularies and tiering — driving greater profits for PBMs through rebates[.]” Nancy Daas, *Prescription Drug Plan Strategies*, Cottingham & Butler (2017), <http://www.cottinghambutler.com/wpcontent/uploads/2017/03/Prescription-Drug-Strategies.pdf>.

<sup>15</sup> Thomas Reinke, *PBMs Just Say No to Some Drugs — But Not to Others*, Managed Care Mag. (Apr. 5, 2015), <https://www.managedcaremag.com/archives/2015/4/pbms-just-say-no-some-drugs-not-others>.

2014, Express Scripts' national formulary was a closed formulary, and clients had to affirmatively opt-out of it.<sup>16</sup>

76. Over the last several years, the PBM Defendants have published annual lists of drug exclusions from formularies. PBMs' exclusion lists are closely analyzed by industry experts who understand that, through these lists, PBMs have the ability to drive health and insurance plan participants and beneficiaries to (or away from) specific drugs.<sup>17</sup> For example, in an August 2, 2016 article about CVS Caremark's and Express Scripts' 2017 formulary exclusions, *Barrons* stated:

Make way for some waves. CVS Health (CVS) and Express Scripts (ESRX) have released their formulary exclusion list for 2017, which details which prescription drugs will not be covered by health plans.

Why do we care?...The coverage list determines whether millions of privately insured individuals can easily use an insurance co-payment to buy their prescriptions. If a drug is excluded, it can dramatically hobble sales.

Thus, the formulary exclusion lists can be used as a tool by insurers and PBMs — leverage you might say — to negotiate with drug

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<sup>16</sup> *Id.*

<sup>17</sup> See, e.g., Kevin McCaffrey, *PBMs Unveil 2017 Formularies, Retain Focus on Exclusions*, *MM&M* (Aug. 2, 2016), <https://www.mmmonline.com/payersmanaged-markets/pbms-unveil-2017-formularies-retain-focuson-exclusions/article/513737/>; Mark Lowery, *2016 Formulary Exclusions in 9 Key Areas*, *Drug Topics: Voice of the Pharmacist* (Aug. 11, 2015), <http://drugtopics.modernmedicine.com/drug-topics/news/2016-formulary-exclusions-9-key-areas>; Bruce Japsen, *PBMs Quietly Gain Leverage As Drug Makers Stumble On Price Hikes*, *Forbes* (Aug. 31, 2016), <https://www.forbes.com/sites/brucejapsen/2016/08/31/pbms-quietly-gain-leverageas-drug-makers-stumble-on-price-hikes/#554d1a3f7ffa>.

makers for better prices [for PBMs and plans].<sup>18</sup>

77. Formulary placement (and potential exclusion) on the health benefit provider formularies is a major factor in the PBM Defendants' negotiations with drug companies (like the Manufacturer Defendants) for rebates and other types of payments. Indeed, the PCMA had admitted that “[i]n classes where several products may be considered therapeutically equivalent, PBMs can negotiate with drug companies for higher rebates[.]”<sup>19</sup>

78. In April 2015, Express Scripts' Chief Medical Officer bragged to *Managed Care Magazine* that formulary exclusions “demonstrate that PBMs [can] move market share.” He further touted that drug companies “[are] now convinced . . . that [PBMs can] actually deliver market share when we [are] motivated to. So we went to the companies, and we told them, ‘We’re going to be pitting you all against each other. Who is going to give us the best price? If you give us the best

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<sup>18</sup> Johanna Bennett, *CVS Health Takes “An Audacious Step” With 2017 Drug Formularies*, Barron’s (Aug. 2, 2016), <https://www.barrons.com/articles/cvshealth-takes-an-audacious-step-with-2017-drug-formularies-1470169569>; *see also Excluded in 2016: These Drugs Are On the Outside Looking In*, Managed Care Mag. (Sept. 10, 2015), <https://www.managedcaremag.com/archives/2015/9/excluded-2016-these-drugs-are-outside-looking>.

<sup>19</sup> Peter Wehrwein, *A Conversation With Steve Miller, MD: Come in and Talk With Us, Pharma*, Managed Care Mag. (April 2015), available at <https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-mdcome-and-talk-us-pharma>.

price, we will move the market share to you. We will move it effectively. We'll exclude the other products.”<sup>20</sup>

79. Similarly, a February 16, 2018 article in *STAT* (a well-known publication focused on the life sciences and pharmaceutical industries) states that PBMs — particularly the PBM Defendants — “[a]s the industry’s heavyweights... now have enormous power over the availability and pricing of essential medicines. Drug makers pay PBMs billions of dollars to ensure their products get preferred positions on formularies, drug lists used to determine which medicines are covered.”<sup>21</sup>

80. Industry experts have further highlighted that the threat of formulary exclusion has yielded substantial payments from drug companies to PBMs. For example, Arthur Shinn of Pharmacy Consultants, LLC stated in a presentation that “[t]he exclusion strategy is a big rebate revenue generator.”<sup>22</sup>

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<sup>20</sup> *Id.*

<sup>21</sup> Casey Ross, *Washington Is Taking Aim at Drug Industry Middlemen. But Can It Break Their Grip on a Captive Market?* *STAT* (Feb. 16, 2018), <https://www.statnews.com/2018/02/16/washington-pharmacy-benefit-managers/>.

<sup>22</sup> “*As the Clock Ticks for Exclusion Opt-Ins, Payers Ponder Access, Disruption, Savings,*” *Drug Benefit News*, Vol. 15, Issue.

**G. Federal and State Government Investigations of Insulin Pricing and “Rebates.”**

81. Various government entities have conducted investigations relating to the allegations described herein. On November 3, 2016, Senator Bernie Sanders and Representative Elijah E. Cummings sent correspondence to the Department of Justice (“DOJ”) and the Federal Trade Commission (“FTC”) requesting that the DOJ and the FTC “investigate whether pharmaceutical companies manufacturing insulin products have colluded or engaged in anticompetitive behavior in setting their drug prices.”<sup>23</sup> The Congressmen noted, among other things, lockstep price increases for the Insulin Drugs.<sup>24</sup>

82. On or about June 2017, Representatives Diana DeGette (D-CO) and Tom Reed (R-NY), the Co-Chairs of the Congressional Diabetes Caucus, conducted a bipartisan inquiry into the dramatic insulin price increases.<sup>25</sup> On November 1, 2018, this caucus published a report that provides an overview of the insulin supply chain, discusses the drivers behind rising insulin prices, and

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<sup>23</sup> See Letter from U.S. Senator Sanders and U.S. Representative Cummings to U.S. Attorney General Loretta Lynch and FTC Chair Edith Ramirez (November 3, 2016), available at <https://www.sanders.senate.gov/download/sanders-cummings-letter-to-doj-ftc-on-insulin?inline=file>.

<sup>24</sup> *Id.* (quoting Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, BLOOMBERG (May 6, 2015)) (emphasis in original).

<sup>25</sup> See *About the Caucus – Goals*, Congressional Caucus on Diabetes, <https://diabetescaucus-degette.house.gov/about>.

recommends policy solutions to lower costs.<sup>26</sup> In its report, the Congressional Diabetes Caucus found that the list price of competing insulin formulations appeared to rise in tandem.

83. In February and April of 2019, the Senate Finance Committee wrote Eli Lilly, Novo, Sanofi, Express Scripts, CVS and Optum, respectively, in order to follow the money trail and better understand how the three largest insulin manufacturers and the three largest PBMs price insulin products.<sup>27</sup> At an April 2019 Congressional hearing, Novo's President, Doug Langa, testified on Novo's perpetuation of the insulin pricing conspiracy alleged herein:

There is this perverse incentive and misaligned incentives (in the insulin pricing system) and this encouragement to keep [reported] prices high. *And we've been participating in that system because the higher the [reported] price, the higher the rebate . . . There is a significant demand for rebates. We spend almost \$18 billion in rebates in 2018 . . . If we eliminate all the rebates . . . we would be in jeopardy of losing [Novo's formulary] positions.*<sup>28</sup> (emphasis added).

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<sup>26</sup> See *Insulin: A life-saving drug too often out of reach*, <https://docs.house.gov/meetings/IF/IF02/20190402/109502/HHRG-116-IF02-20190402-SD001.pdf> (“Congressional Diabetes Caucus Report”); see also <https://diabetespac.org/report-on-insulin/>.

<sup>27</sup> See, e.g., *Grassley, Wyden Launch Bipartisan Investigation into Insulin Prices*, GRASSLEY.SENATE.GOV, <https://www.grassley.senate.gov/news/news-releases/grassley-wyden-launch-bipartisan-investigation-insulin-prices>.

<sup>28</sup> *Priced Out Of A Lifesaving Drug: Getting Answer On The Rising Cost Of Insulin*, Hearing Before the Subcomm. on Energy and Commerce (April 10, 2019).

84. On July 28, 2016, Eli Lilly disclosed that the U.S. Attorney's Office for the Southern District of New York issued a civil investigative demand for information related to contracts with services performed by and payments to PBMs.<sup>29</sup>

85. On May 1, 2017, Eli Lilly announced in a Securities and Exchange Commission filing that it had received civil investigative demands in connection with insulin pricing investigations by the Attorneys General for the States of Washington and New Mexico.<sup>30</sup>

86. The Attorney General for the State of Washington also sent a civil investigative demand to Sanofi regarding insulin pricing and trade practices.<sup>31</sup>

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<sup>29</sup> 2016 Form 10-Q, Eli Lilly and Company, at 45, <https://investor.lilly.com/static-files/4ff44c76-ec31-44c4-a032-0691d3e2879f>.

<sup>30</sup> See 2017 Form 10-Q, Eli Lilly and Company (May 1, 2017), <https://investor.lilly.com/secfiling.cfm?filngID=59478-17-129&CIK=59478>.

<sup>31</sup> See 2017 Half-Year Financial Report, at 41, Sanofi, [https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/0000-2999/2017\\_Half\\_Year\\_Financial\\_report.pdf?la=en&hash=4EB9683701B2D794B9C98A6DE56D0470](https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/0000-2999/2017_Half_Year_Financial_report.pdf?la=en&hash=4EB9683701B2D794B9C98A6DE56D0470).

87. In January 2017, the Attorney General for the State of Minnesota launched civil investigations into Sanofi<sup>32</sup> and Novo<sup>33</sup> regarding the companies' insulin pricing and trade practices.

**V. Defendants' Kickback Scheme - PBMs Solicit and Receive Kickbacks for Formulary Placement From the Manufacturers That Were Not Payment for Services Actually Rendered.**

88. PBM Defendants generally pass through only a portion of specified "rebates" they demanded from drug manufacturers to health benefit provider clients.<sup>34</sup> Moreover, PBMs have written their contracts to retain for themselves all other payments from drug companies like the Manufacturer Defendants, including, among other things, discounts, "administrative or other fees," and/or side deals, and thus, the PBM Defendants keep substantially more of the moneys received from drug makers than they pass through. The result is that the PBM Defendants

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<sup>32</sup>See 2016 Form 20-F, Sanofi, at 183, <https://www.sec.gov/Archives/edgar/data/1121404/000119312517069257/d245496d20f.htm>.

<sup>33</sup> See 2016 Annual Report, Novo Nordisk, [http://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE\\_NVO\\_2016.pdf](http://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2016.pdf).

<sup>34</sup> *It's Time To Determine How Much Your PBM Is Depriving Your Plan of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition, <http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/>.

profit handsomely from “rebates.”<sup>35</sup> And the Plaintiffs, as described herein, have been injured because the price they paid and continue to pay for the Insulin Drugs was and is artificially inflated as a result of the Defendants’ illegal schemes, acts, and conspiracy.

89. Plaintiffs and Class members do not know, and could not know, the details of the financial arrangement between PBM Defendants and Manufacturer Defendants. These contracts are closely kept trade secrets.

90. In addition to rebates, drug companies like the Manufacturer Defendants often pay PBM Defendants substantial amounts of various “administrative fees” in exchange for, among other things, ensuring a given drug’s formulary placement.<sup>36</sup> As Express Scripts states in its template contract with the City of Flint, Michigan:

ESI [Express Scripts] provides administrative services to formulary rebate contracted manufacturers, which include, for example,

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<sup>35</sup> “How to Dramatically Decrease Your MCO’s Rx Coverage Costs,” Managed Care, April 1, 2008, <https://www.managedcaremag.com/archives/2008/4/how-dramatically-decrease-your-mco-s-rx-coverage-costs>.

<sup>36</sup> Henry C. Eickelberg, *The Prescription Drug Supply Chain “Black Box” — How it Works and Why You Should Care*, Am. Health Pol’y Inst. (2015), <http://www.americanhealthpolicy.org/Content/documents/resources/December%202015%20Study%20Understanding%20the%20Pharma%20Black%20Box.pdf>; *see also* Linda Cahn, *It’s Time To Determine How Much Your PBM Is Depriving Your Plan Of Rebates: File An “Accounting” Procedure*, Nat’l Prescription Coverage Coalition (NPCC), <http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-anaccounting-procedure/>.

maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price, or (ii) 5.5% of the wholesale acquisition cost of the products. In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These service fees are not part of the formulary rebates or associated administrative fees.<sup>37</sup>

91. An industry expert, Linda Cahn observed “[i]f a PBM enters into contracts with drug companies and chooses to give rebates another name — like administrative fees or health management fees or grants — the PBM will arguably eliminate its obligation to pass through the financial benefits to its clients.”<sup>38</sup> Additionally, “a PBM can deprive its clients of rebates by ensuring the rebates are paid on the basis that is not attributable to the clients’ drug purchases.”<sup>39</sup>

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<sup>37</sup> Sample Form of PBM Agreement with Express Scripts, Inc., Genessee County (Flint, Michigan) Purchasing Department (February 27, 2015), <http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage.pdf>.

<sup>38</sup> Linda Cahn, *Don’t Get Trapped By PBM’s Rebate Labeling Games*, Managed Care (Jan. 1, 2009), <https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games>.

<sup>39</sup> *Id.*

92. PhRMA, an industry group of pharmaceutical manufacturers, has explained:

In addition to rebates, PBMs often *require* manufacturers to pay administrative service fees for administering, invoicing, and collecting rebate payments. These administrative fees are intended to reimburse the PBM for services provided to the manufacturer and are not generally passed on to the PBM's client.<sup>40</sup>

93. Altarum, a nonprofit research and consulting organization that works with governments and private insurers to improve health outcomes for Medicare and Medicaid beneficiaries, stated:

The concern is that PBMs, in their role as intermediaries, have diverted much of the potential savings to their own bottom lines, a concern intensified by the lack of transparency around the proprietary rebate amounts. Examples include PBMs retaining more than their agreed upon share of rebates through re-labeling rebates as fees and PBMs pressuring manufacturers to increase their list prices with a commensurate increase in rebates. This benefits PBMs doubly since they are often paid a percentage of list price and also retain a share of rebates.<sup>41</sup>

94. For example, in a February 14, 2017 letter to HHS, regarding PBM practices, Eli Lilly stated that:

[There] is an emerging practice by some (but certainly not all) of these [PBM] entities to condition a manufacturer's ability to bid for federal government business on the willingness of manufacturer[s] to accept a non-negotiable suite of administrative services at a non-negotiable

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<sup>40</sup> *Follow the Dollar*, PhRMA (Nov. 2017), at 8, <http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf> (emphasis added).

<sup>41</sup> Charles Roehrig, *The Impact of Prescription Drug Rebates on Health Plans and Consumers*, Altarum (Apr. 2018), at 4.

rate. From Lilly's perspective, this is in effect a "pay-to-play" requirement.<sup>42</sup>

Thus, according to Eli Lilly, PBMs are demanding and drug companies are paying what are labelled administrative fees (which do not flow to the health benefit providers to any significant extent) to PBMs in exchange for formulary placement.

95. Administrative fees can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to David Dross, a pharmacy-benefits consultant who has been cited in Senate testimony, administrative fees can amount to 25-30% of total payments from drug companies like the Manufacturer Defendants.<sup>43</sup> Express Scripts revealed in a 2017 lawsuit that it filed against one drug manufacturer that it kept 13 times more in administrative fees than it passed back to its clients through "rebates."<sup>44</sup>

96. That the PBM Defendants have, in fact, retained increasing amounts of rebates and fees for themselves is demonstrated by a March 2019 Pew Center

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<sup>42</sup> Letter from Josh O'Harra, Assistant General Counsel for Eli Lilly, to Patrice Drew, Office of the Inspector General, February 14, 2017, <https://www.regulations.gov/document?D=HHSIG-2017-0001-0002>.

<sup>43</sup> David Dross, *Will Point-of-Sale Rebates Disrupt the PBM Business?* Mercer (July 31, 2017), <https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html>.

<sup>44</sup> According to Express Scripts' complaint, it entered into "rebate agreements" with the drug manufacturer, which required the manufacturer to pay Express Scripts far more in "administrative fees" than the manufacturer paid in "formulary rebates." <http://nationalprescriptioncoveragecoalition.com/express-scripts-lawsuit-should-raise-everyones-eyebrows/>.

study which analyzed manufacturer rebate levels, health-plan drug expenditures and PBM revenues from drug expenditures during this period.<sup>45</sup> That study found that even though manufacturers paid greater rebates during the period 2012-2016<sup>46</sup>, those rebates did not actually reduce health-plan expenditures on drugs — which increased by 66% from 2012-2016.<sup>47</sup> The report observed that as health benefit providers were being forced to spend more and more on drugs, PBM revenues virtually doubled because they retained increased percentages of rebates for themselves and increasingly took their payments from manufacturers in the form of “fees” that they did not share with their health benefit provider clients.

97. The Pew Center study estimated that:

- in 2012, PBMs retained \$11.6 billion in rebates and fees related to drug expenditures (which was composed of \$5.7 billion in manufacturer rebates and \$5.9 billion in manufacturer fees),
- by 2015 (3 years later), PBMs retained \$18.2 billion in rebates and fees related to drug expenditures (which was composed of \$7.8 billion in manufacturer rebates and \$10.4 billion in manufacturer fees), and

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<sup>45</sup> *The Prescription Drug Landscape Explored, A look at retail pharmaceutical spending from 2012 to 2016*, March 2019 Pew Center Report, <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored>.

<sup>46</sup> Manufacturer rebates increased from \$10.2 billion in 2012 to \$29.1 billion in 2016. *Id.* at 9.

<sup>47</sup> In 2012, \$110.6 billion in commercial health plan premiums went to pay for retail prescription drugs, and by 2016 \$183.9 billion of commercial health plan premiums went to pay for retail prescription drugs — a 66% increase in drug expenditures over a four-year period. *Id.* at 8.

- by 2016 (4 years later), PBMs retained \$22.4 billion in rebates and fees related to drug expenditures (which was composed of \$5.8 billion in manufacturer rebates and \$16.6 billion in manufacturer fees).<sup>48</sup>

98. Thus, over a four-year period, due to surging prices based on Defendants' conduct, PBM revenues virtually doubled (from \$11.6 billion to \$22.4 billion) because PBMs retained more and more manufacturer rebates and fees (which are not shared with health benefit provider clients) virtually tripled. Notably, PBM-retained monies increased not only in total dollar terms, but also as an increasing percentage of total drug expenditures.

99. While the PBM Defendants pass some percentage of rebates and fees back to the plans, they also retain a large portion of such moneys, in part through misleading labeling of what is essentially kickback payments received from drug companies like the Manufacturer Defendants. This lack of transparency enables the PBM Defendants' to label the payments that they negotiate with the Manufacturer Defendants such that they retain control over the amount of kickbacks they keep for themselves. Thus, the hard bargains the PBM Defendants purport to drive for their clients are, in reality, for the benefit of the PBM Defendants themselves.

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<sup>48</sup> *Id.* at 13.

100. These rebates and fees solicited by the PBM Defendants and paid to them by the Manufacturer Defendants as described herein were payments other than for services rendered, *i.e.*, commercial bribes and kickbacks, and constituted a breach of the fiduciary duty owed by the PBM Defendants to their clients. Thus, in purpose and effect these rebates and payments of fees constituted commercial bribery through unlawful kickbacks.

101. The PBM kickbacks were and continue to be paid from the difference between the Defendants' published WAC prices and the net selling prices secretly agreed upon by the Manufacturer Defendants and the PBMs. The prices paid by Plaintiffs and Class members to the Manufacturer Defendants for the Insulin Drugs were artificially inflated as part of the illegal schemes, acts, and conspiracy described herein, and the revenue generated by the artificially inflated prices is used by them to pay PBM Defendants the kickbacks as so-called "rebates" and "fees."

102. The spread was significant to the Defendants because it was the source of the money funding the kickbacks that the Manufacturer Defendants paid the PBM Defendants.

103. The Manufacturer Defendants improperly inflated the WAC prices of their Insulin Drugs and used the increased monies they received to pay the PBM Defendants the kickbacks.

104. When a Manufacturer Defendant enlarges the spread in order to pay higher kickbacks, Plaintiffs and Class members are forced to pay the higher prices.

105. In a well-functioning, competitive market for products like the Insulin Drugs, PBMs would exercise the leverage they possess by virtue of their role in creating and managing formularies to negotiate lower prices from drug companies, including the Manufacturer Defendants.

106. In turn, the Manufacturer Defendants would compete by providing the lowest price in order to obtain a favorable position on the formulary.

107. In other words, a competitive price would provide a legitimate basis to confer formulary status to the least costly medication.

108. However, during the last decade the PBM Defendants have demanded bribes and kickbacks to eliminate the price-disciplining effects from competition. Because so much of the rebates and fees flow into the PBM Defendants' coffers (rather than being paid to their clients), the PBM Defendants benefit from higher WAC prices because it results in higher rebate and fee payments that they keep for themselves (even though doing so is contrary to the interests of the PBMs' health benefit provider clients).

109. The kickbacks that the PBM Defendants receive for a drug are usually calculated as a percentage of the dollar value of a drug's usage based on its WAC list price — such as 30% of a drug's total unit volume purchases by the PBM's

clients multiplied by the WAC list price per unit. The total amount of a drug's sales (and thus the total amount of the rebates and fees paid to a PBM for that drug) are driven by two factors: a drug's list price (WAC or AWP, which is typically WAC plus 20%), and its sales volume. For example, the total purchase amount for 1000 units of a \$300 drug is \$300,000, and the total purchase amount for 1000 units of a \$100 drug is \$100,000. If a PBM receives a 30% rebate for both drugs, then the PBM receives \$90,000 in rebates for the \$300 drug, and \$30,000 for the \$100 drug.

110. Furthermore, the PBM Defendants benefit from large, annual list price increases by drug companies that occur during the life of a multi-year contract for two reasons. First, increases in a drug's list price increase the dollar-amount of the rebate and fee payments that the PBMs get to keep. For example, if a PBM receives a 30% rebate on 1000-unit sales of a \$300 drug, if the drug price increases by \$100 per unit, then the PBM's rebates increase by \$30,000 (from \$90,000 to \$120,000).

111. In addition, large drug price increases during a multi-year contract can generate additional fees and rebates to PBMs in the form of "price-protection" benefits that PBM Defendants do not share with their health benefit provider clients. A recent report on the drug industry noted that, in addition to rebates used to purchase formulary access and market share, price/inflation protection rebates

also incentivize drug companies to raise list prices and thereby pay PBM

Defendants for formulary placement:

At the whole-market level, we sense that the price protection rebate arbitrage game is driving manufacturers to higher list price increases than would otherwise occur[.] . . . Price protection rebates between brand manufacturers and PBMs are common, as are fixed rebate agreements between PBMs and a significant portion of their plan sponsors. When brand manufacturers' [list price] increases exceed the price protection threshold, the manufacturers rebate the difference to PBMs, who pocket the difference when these price protection rebates grow faster than the PBMs' fixed rebate commitments to plan sponsors. Thus all else equal in a given category, the product with the more rapid list price increases is more profitable to the PBM. Manufacturers, realizing this, don't want their products disadvantaged, and accordingly are driven to keep their rates of list price inflation at least as high, and ideally just a bit higher, than peers'. Durable list price inflation is the natural result.<sup>49</sup>

112. As OptumRx's CEO candidly admitted in an October 15, 2016 interview with Modern Healthcare, "the largest players" in the PBM industry — the PBM Defendants — "actually benefit from price increases."<sup>50</sup>

113. This has created a perverse incentive for: (a) the PBM Defendants to give preferential formulary status to higher-priced drugs which come with higher payments to the PBMs, even if doing so is contrary to the health plan clients'

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<sup>49</sup> Richard Evans, Scott Hinds, & Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16*, SSR LLC, 36 (Oct. 5, 2016).

<sup>50</sup> *Q&A: We Don't Set the Price. Pharmaceutical Manufacturers Set the Price*, Mod. Healthcare (Oct. 15, 2016), <http://www.modernhealthcare.com/article/20161015/MAGAZINE/310159957>.

interest in favoring lower-priced drugs; and (b) for drug companies such as the Manufacturer Defendants to use high rebate and fee payments to purchase favorable formulary status from PBM Defendants, instead of trying to ensure favorable formulary status by lowering list prices or limiting list price increases.

114. The PBM Defendants' interest and benefit in favoring high-priced drugs and large price increases (contrary to their clients' interests) makes them ripe targets to be bribed by brand manufacturers such as the Manufacturer Defendants who pay kickbacks (*i.e.*, rebates and fees that flow to the PBM Defendants) to gain the ability to raise list prices without being penalized by the PBMs.

115. A February 2018 white paper issued by the White House Counsel of Economic Advisors states that, through the negotiation of secret rebates, PBMs generate enormous profits for themselves while at the same time inducing drug companies to increase their list prices:

[T]he PBM market is highly concentrated. Three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves. Over 20 percent of spending on prescription drugs was taken in as profit by the pharmaceutical distribution system. *The size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret. The system encourages manufacturers to set artificially high list prices[.]*<sup>51</sup>

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<sup>51</sup> *Reforming Biopharmaceutical Pricing at Home and Abroad*, White House Counsel of Econ. Advisors (Feb. 2018), <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf> (citations omitted).

116. Manufacturer Defendants' executives have readily admitted that the price increases are directly tied to — and the result of — the bribes and kickbacks to PBM Defendants. For example, an October 2016 *Wall Street Journal* article reported that Enrique Conterno (president of Eli Lilly's diabetes business) stated that:

The reason drugmakers sharply raise list prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists.<sup>52</sup>

117. Similarly, Novo stated in a 2016 open letter that “as the rebates, discounts and price concessions got steeper, we were losing considerable revenue .... So, we would continue to increase the list [price] in an attempt to offset the increased rebates, discounts and price concessions to maintain a profitable and sustainable business.”<sup>53</sup>

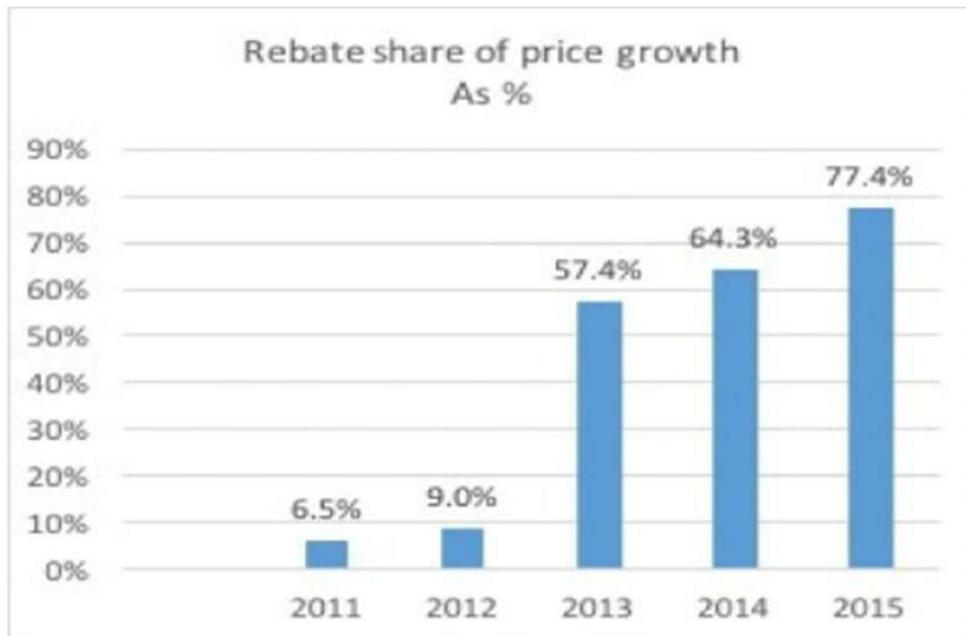
118. As a result of this scheme, drug company payments to PBMs for favorable formulary placement now account for the vast majority of drug list price increases over the last several years. A study conducted by the non-profit, non-partisan Center for Medicine in the Public Interest estimates that, from 2011-2015,

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<sup>52</sup> Denise Roland and Peter Loftus, “*Insulin Prices Soar While Drugmakers' Share Stays Flat*,” The Wall Street Journal (Oct. 7, 2016).

<sup>53</sup> Jakob Riis, President, Novo Nordisk Inc., *Perspectives from NNI President Jakob Riis on pricing and affordability*” (Nov. 30, 2016).

rebates paid to PBMs grew as a percentage of total manufacturer list price increases from 6.5% to an astounding 77.4%. In 2016, these rebates accounted for 79% of total manufacturer list price increases.<sup>54</sup>



119. As PBM Defendants have demanded larger and larger rebates from drug companies over the last several years — and drug prices have risen — PBM Defendant revenues have soared.<sup>55</sup>

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<sup>54</sup> See Robert Goldberg, Ph.D., *Reduce Drug Prices by Cutting Out PBM Rebates*, DrugWonks.com (Apr. 15, 2016); Robert Goldberg, Ph.D., *Most of the Increase in Drug Spending Pocketed By PBMs and Insurers: What the Media Missed in Covering the IMS Drug Cost Study*, DrugWonks.com (Apr. 15, 2016), <http://drugwonks.com/blog/most-of-the-increase-in-drug-spending-pocketed-by-pbms-and-insurers>.

<sup>55</sup> CVS Caremark's Pharmacy Services Segment saw revenues climb from \$76 billion in 2013 to more than \$120 billion in 2016. Between 2010 and 2016, Express Scripts' revenue jumped from approximately \$45 billion to north of \$100 billion. OptumRx's revenue increased from roughly \$32 billion in 2014 to more than \$60 billion in 2016. And Prime Therapeutics' revenues rose from \$1.8 billion

## **VI. Defendants' Price-Fixing Scheme**

### **A. Manufacturer Defendants Increased the Insulin Drug Prices in Lockstep.**

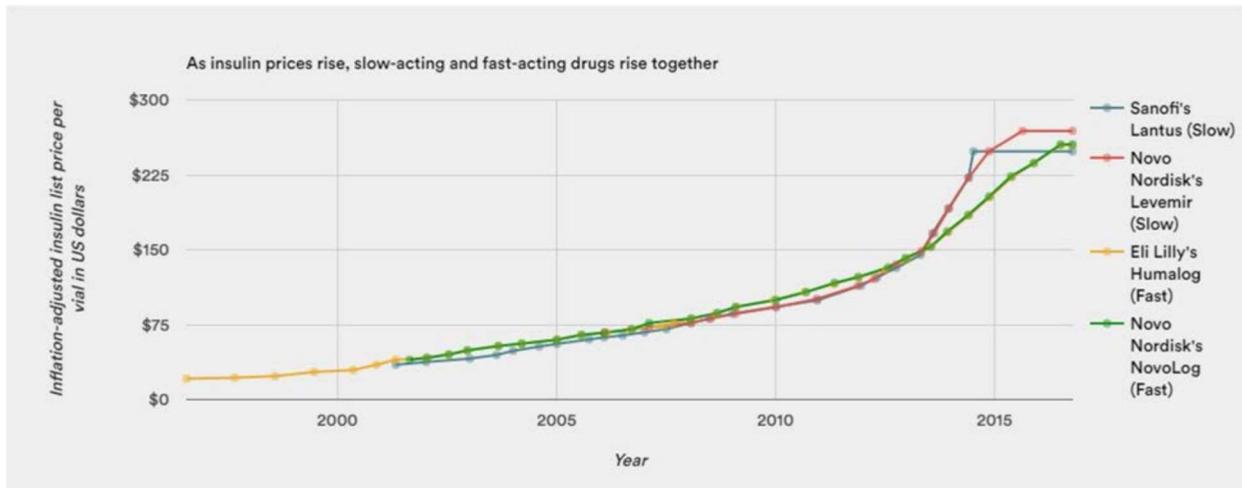
120. The prices for the Insulin Drugs manufactured and sold by the Manufacturer Defendants have increased in lockstep since 2012.

121. Figure 2 shows the dramatic lockstep price hikes imposed by Manufacturer Defendants for the Insulin Drugs from 2000 to 2015.

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in 2012 to \$4.73 billion in 2016. As of December 31, 2017, Express Scripts reported annual drug company payments of \$2.58 billion, representing approximately 37% of its total net receivables. According to Professor Ed Ketz of Penn State, given the significant percentage of total net receivables from drug companies, “we can start thinking of the pharmaceutical companies as customers. They’re not just bystanders in this equation.” Linette Lopez, “The Feds just asked a huge healthcare company who their real clients are and the answer is totally unsatisfying,” Business Insider US (Dec. 7, 2017), <http://www.businessinsider.com/sec-looks-into-express-scripts-rebates-from-pharmaceutical-firms-2017-12>.

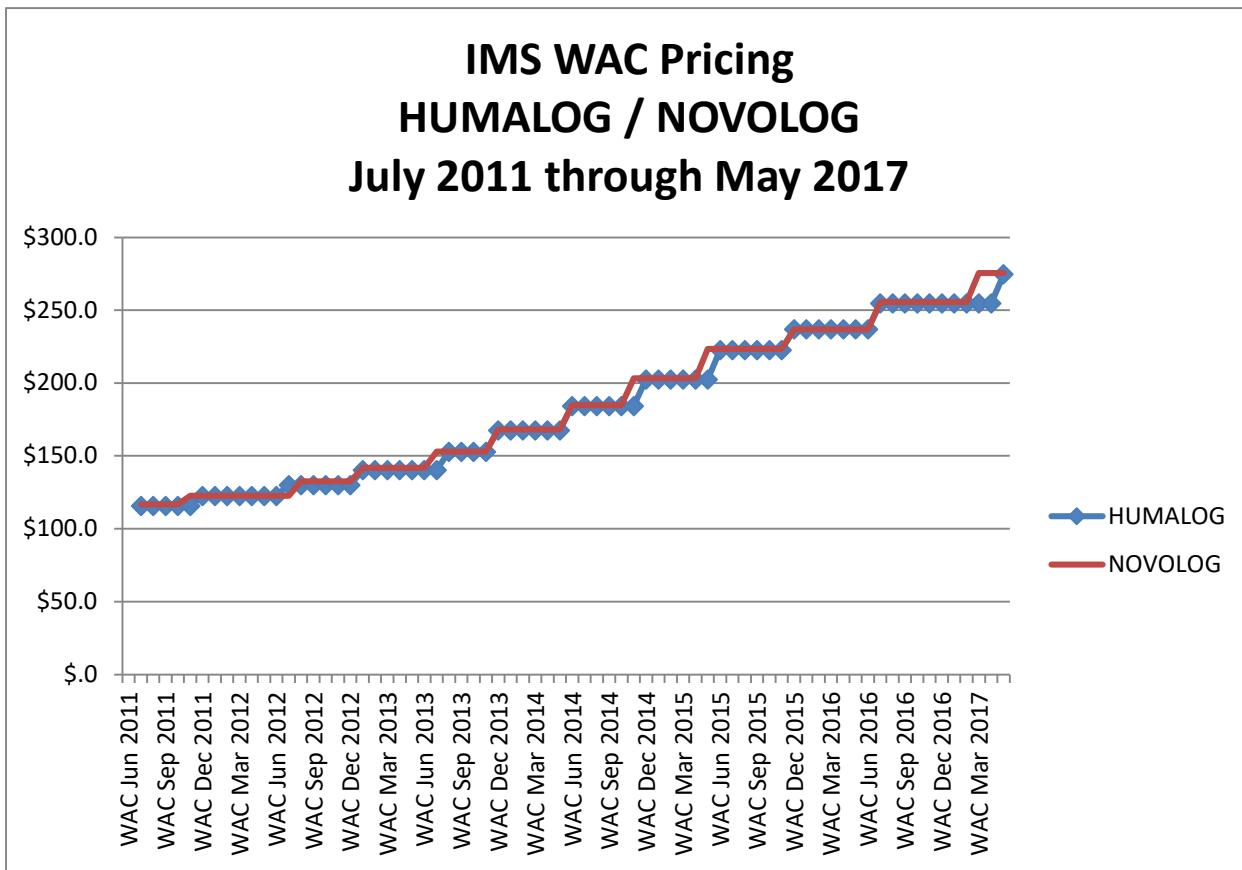
**Figure 2: Rising insulin prices from 2000-2015<sup>56</sup>**



122. Figure 3 demonstrates price increases shown in IMS Health data for NovoLog and Humalog 100 unit/10 ML vials between July 2011 and May 2017. These price increases demonstrate the highly tethered relationship between the Direct Purchaser Price and the inflated WAC prices.

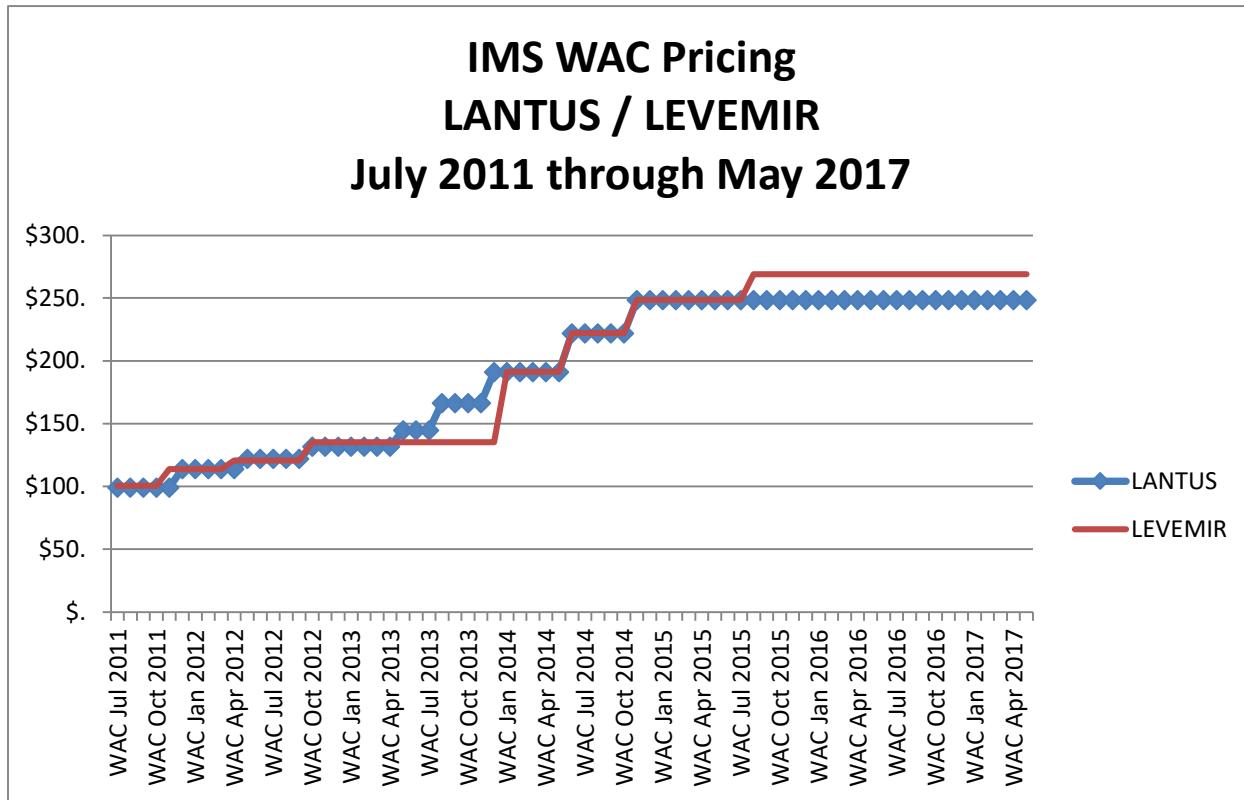
<sup>56</sup> Rebecca Robbins, *The Insulin Market is Heading for a Shakeup. But Patients May Not Benefit*, STAT (Oct. 14, 2016), <https://www.statnews.com/2016/10/14/insulin-prices-generics/>.

**Figure 3: Price Increases for NovoLog and Humalog July 2011 – May 2017**



123. Figure 4 demonstrates the lockstep price increases shown in IMS Health data for Lantus and Levemir 100 unit/10 ML vials between July 2011 and May 2017. These price increases demonstrate the highly tethered relationship between the Direct Purchaser Price and the inflated WAC prices.

**Figure 4: Price Increases for Lantus and Levemir July 2011 – May 2017**



124. Although drug companies usually rely on their research and development costs or purported improvements in the “clinical benefits” of their drugs to rationalize high pharmaceutical prices, the Manufacturer Defendants’ price hikes for the Insulin Drugs are unrelated to those factors.

125. In fact, the clinical benefits of these medications have not changed for many years. For example, Levemir and Novolog are the exact same drugs they were 10 years ago, but the Manufacturer Defendants continue to increase the prices of those drugs dramatically every year.

126. These lockstep insulin prices cannot be explained by normal competitive forces.

127. The actual cause of the rapidly escalating prices was an unlawful scheme to artificially increase prices, the result of an agreement among Defendants to increase pricing and restrain competition for the sale of the Insulin Drugs in the U.S.

128. Throughout the Class Period, Defendants engaged in a continuing contract, combination or conspiracy among themselves in which they agreed to fix, maintain, and stabilize prices of the Insulin Drugs.

129. The purpose and actual effect of this ongoing contract, combination and conspiracy was to cause Plaintiffs and Class members to pay artificially inflated prices that were above the prices that would have existed if a competitive market had determined prices for the Insulin Drugs.

## **B. In Person Meetings**

130. Defendants were members of trade associations, which they used to facilitate their conspiratorial communications and implement their anticompetitive scheme to raise, maintain, and stabilize prices of the Insulin Drugs, including, but not limited to conferences and events held by the Pharmaceutical Care Management Association (“PCMA”) and the American Society of Health-System Pharmacists (“ASHP”).

131. PCMA is the “national association representing America’s PBMs.”<sup>57</sup>

The PCMA holds three conferences each year, the Annual Conference, the sPCM Business Forum, and a PBM Policy Forum. Before and during the Class Period, Defendants attended the Annual Conference and the sPCM Business Forum each year.

132. The ASHP is a professional organization that represents pharmacists who serve as patient care providers in acute and ambulatory settings.<sup>58</sup> ASHP’s nearly “55,000 members include pharmacists, student pharmacists, and pharmacy technicians.”<sup>59</sup> The ASHP held periodic meetings similar to the PCMA.

133. Before and during the Class Period, Manufacturer Defendants attended multiple PCMA Annual Conferences, sPCM Business Forums, and ASHP meetings. In addition, PBMs were also in attendance. For example:

- On December 2–6, 2012, Defendants Eli Lilly, Novo, and Sanofi all attended and presented at the 2012 ASHP Midyear Clinical Meeting and Exhibition in Las Vegas, Nevada.
- On March 12 & 13, 2014, Defendants Eli Lilly, Novo, and Sanofi all attended the 2014 sPCM Business Forum at JW Marriott Orlando Great Lakes in Orlando, Florida.
- On October 13 and 14, 2014, Defendants Eli Lilly, Novo, and Sanofi all attended the 2014 PCMA Annual Meeting together at the Terranea Resort in Ranch Palos Verdes, California.

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<sup>57</sup> See *About*, Pharmaceutical Care management Association, PCMANET.ORG, <https://www.pcmanet.org/about/>.

<sup>58</sup> *About ASHP*, ASHP.ORG, <https://www.ashp.org/About-ASHP>.

<sup>59</sup> *Id.*

- On December 7–11, 2014, Defendants Eli Lilly, Novo, and Sanofi all attended and presented at the 2014 ASHP Midyear Clinical Meeting and Exhibition in Anaheim, California.
- On March 16 & 17, 2015, Defendants Eli Lilly and Novo attended the 2015 sPCMA Business Forum at the Hilton Bonnet Creek in Orlando, Florida.
- On September 21 & 22, 2015, Defendants Eli Lilly, Novo, and Sanofi all attended the 2015 PCMA Annual Meeting at the Broadmoor in Colorado Springs, Colorado.
- On February 8 & 9, 2016, Defendants Eli Lilly, Novo, and Sanofi all attended the 2016 sPCMA Business Forum held at the JW Marriott Orlando Grande Lakes in Orlando, Florida.
- On September 19 & 20, 2016, Defendants Eli Lilly, Novo, and Sanofi all attended and sponsored the 2016 PCMA Annual Meeting.
- On December 4–8, 2016 Defendants Eli Lilly, Novo, and Sanofi all attended and presented at the 2016 ASHP Midyear Clinical Meeting and Exhibition in Las Vegas, Nevada.
- On March 8 & 9, 2017, Defendants Eli Lilly, Novo, and Sanofi all attended the 2017 sPCMA Business Forum at the Hilton Bonnet Creek in Orlando, Florida.
- On September 25 & 26, 2017, Defendants Eli Lilly, Novo, and Sanofi all attended and sponsored the 2017 PCMA Annual Meeting at the Westin Kierland in Scottsdale, Arizona.
- On March 5 & 6, 2018, Defendants Eli Lilly, Novo, and Sanofi all attended the 2018 sPCMA Business Forum at the Hilton Bonnet Creek in Orlando, Florida.
- On September 24 & 25, 2018, Defendants Eli Lilly, Novo, and Sanofi all attended the 2018 PCMA Annual Meeting at the Westin Kierland in Scottsdale, Arizona.
- On March 11 & 12, 2019, Defendants Eli Lilly, Novo, and Sanofi all attended the 2019 sPCMA Business Forum at the Hilton Bonnet Creek in Orlando, Florida.
- On September 23 & 24, 2019, Defendants Eli Lilly, Novo, and Sanofi all attended the 2019 PCMA Annual Meeting at the Westin Kierland in Scottsdale, Arizona.
- On December 8–12, 2019, Defendants Eli Lilly, Novo, and Sanofi all attended the 2019 ASHP Midyear Clinical Meeting and Exhibition in Las Vegas, Nevada.

134. As a result of these numerous interactions over the years, Defendants' employees are often aware of their competition's current and future business plans. This familiarity and opportunity, on information and belief, led to agreements among competitors to raise and fix prices so as to avoid competing with one another on price.

135. Further, Defendants' attendance at the above conferences allowed for face-to-face meetings between Defendants and thus opportunities for communications between Defendants relating to bids and pricing strategy.

136. During the Class Period, the Manufacturer Defendants were also in regular communication with the PBM Defendants regarding pricing, price protection, and rebates.

137. The Manufacturer Defendants raised the Insulin Drugs prices within about one to two months after the above conferences and meetings.

**C. The Analog Insulin Markets are Highly Susceptible to Collusion.**

138. The relevant markets for analog insulin (long-acting and rapid-acting) are highly concentrated and dominated by Defendants, who control the entire market for analog insulin.

139. There are significant barriers to entry in the relevant analog insulin market. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are high barriers to entry in the brand name drug market.

Barriers to entry increase the relevant market's susceptibility to a coordinated effort among the dominant entities in the industry to maintain supra-competitive prices.

140. Analog insulin sales operate in an inelastic market. In an inelastic market, an increase in price results in a relatively small decline or no decline in demand for the product despite the price increase, because of the need for the product and the lack of substitutes. Analog insulin is a necessary treatment for millions of diabetes patients.

141. Millions of diabetes patients depend on the Insulin Drugs medication marketed and sold by Manufacturer Defendants. In light of the absence of competition and barriers to the relevant market, many patients are unable to substitute cheaper medications for the Insulin Drugs.

142. Defendants have maintained supra-competitive pricing for the Insulin Drugs during the Class Period.

## **VII. Interstate Trade and Commerce**

143. As described herein, during the Class Period, Manufacturer Defendants, directly or through one or more of their affiliates, sold the Insulin Drugs throughout the U.S. in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

144. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

145. Defendants' and their co-conspirators' conduct, including the marketing and sale of the Insulin Drugs, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the U.S.

146. The conspiracy alleged in this pleading has directly and substantially affected interstate commerce as Defendants deprived Plaintiffs and Class members of the benefits of free and open competition in the purchase of the Insulin Drugs within the U.S.

147. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of the Insulin Drugs, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing the Insulin Drug prices, was intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the U.S. and on import trade and commerce with foreign nations.

### **VIII. Antitrust Injury**

148. Defendants' contract, combination or conspiracy with regard to the prices of Insulin Drugs had the following anticompetitive effects in the relevant market for the Insulin Drugs:

- a. Competition in the relevant market for the Insulin Drugs has been reduced;

- b. Prices for the Insulin Drugs have been artificially maintained and increased despite the existence of competing manufacturers for each drug; and
- c. U.S. purchasers have been deprived of the benefit of price competition in the relevant market for the Insulin Drugs.

149. As described herein, during the Class Period, Plaintiffs and Class members directly purchased the Insulin Drugs from the Manufacturer Defendants. As a result of the Defendants' anticompetitive conduct, including price fixing and commercial bribery, Plaintiffs and Class members paid more for the Insulin Drugs than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes compensable harm under the federal antitrust laws.

150. Because Defendants' unlawful conduct has successfully eliminated competition in the relevant market, Plaintiffs and Class members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid for the Insulin Drugs. The full amount of such damages will be calculated after discovery and upon proof at trial.

151. Defendants' misconduct reduced competition in the Insulin Drugs markets, reduced choice for purchasers, and caused injury to purchasers.

152. Defendants' anticompetitive conduct is ongoing, and, as a result, Plaintiffs and Class members continue to pay supra-competitive prices for the Insulin Drugs.

## **IX. Fraud, Fraudulent Concealment and Equitable Tolling**

153. During the Class Period, Defendants affirmatively and fraudulently concealed their unlawful conduct against Plaintiffs and Class members.

154. Because of Defendants' active concealment, Plaintiffs and Class members had no knowledge of Defendants' unlawful conduct as alleged herein or of facts sufficient to place them on inquiry notice of the claims set forth herein, until at least November of 2016.

155. To facilitate their illegal commercial bribery, kickback and price fixing scheme, Defendants carefully concealed evidence of their unlawful conduct and their pricing structures and sales figures for the Insulin Drugs. In particular, each Defendant concealed the fact that Defendants agreed to increase prices in order to fund their payments to PBMs for favorable formulary placement.

156. Defendants went to great lengths to conceal their program of kickbacks and collusion to increase prices to pass along the costs of rebates to PBM to direct purchasers, even concealing it from investors. For instance, Novo concealed its relationship with PBMs, preventing investors from obtaining accurate information regarding Novo's insulin sales. In Novo's 2015 Annual Report, the company stated its "[p]roduct success is largely based on competition on efficacy, safety, quality and price." Novo (and all of the other Defendants) knew that the

selection of the Insulin Drugs for formulary placement was driven by the kickbacks, not efficacy, safety, quality or price.

157. Information regarding the government investigation of Defendants' alleged unlawful conduct in the analog insulin market was not made public until November 2016.

158. Given the government's role as the single largest healthcare payor in the U.S., the government's inability to uncover any evidence of Defendants' unlawful scheme to artificially raise and fix prices until late 2016 demonstrates that Plaintiffs and Class members could not have discovered Defendants' illegal conduct prior to that time.

159. Further, Defendants made misleading public statements regarding rebates, price increases and their actual profits from the sale of insulin drugs.

160. For example, in Novo's 2009 and 2011 Annual Reports it stated:

Customer rebates are offered to a number of managed healthcare plans. These rebate programmes provide that the customer receives a rebate after attaining certain performance parameters relating to product purchases, formulary status and pre-established market share milestones relative to competitors.<sup>60</sup>

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<sup>60</sup> See 2009 and 2011 Annual Reports, Novo Nordisk, [https://www.novonordisk.com/content/dam/Denmark/HQ/investors/irmaterial/annual\\_report/2010/20100203\\_Annual%20Report%202009\\_UK.pdf](https://www.novonordisk.com/content/dam/Denmark/HQ/investors/irmaterial/annual_report/2010/20100203_Annual%20Report%202009_UK.pdf), at 56; [https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE\\_NVO\\_2011.pdf](https://www.annualreports.com/HostedData/AnnualReportArchive/n/NYSE_NVO_2011.pdf), at 60.

161. In Novo's 2013 Annual Report it stated:

The principal market risks Novo Nordisk experiences are:

- price pressure and reimbursement restrictions by payers
- the launch of new products by established competitors
- increased competition from producers of biosimilar medicines in key markets. Europe, China and the US are all main markets for Novo Nordisk where payers – both governments and private payers – take measures to limit spending on medicines, typically by driving down prices, demanding higher rebates and/or restricting access to and reimbursement of products.<sup>61</sup>

162. In Novo's 2014 Annual Report, Novo stated:

These sales drivers are expected to be partly countered by an impact from increased rebate levels in the US, intensifying competition within diabetes and biopharmaceuticals as well as macroeconomic conditions in a number of markets in International Operations.<sup>62</sup>

#### IMPACT OF US REBATES

A significant factor in net operating assets also relates to movement in the provision for sales rebates in the US, presented as Short-term provisions in the balance sheet. The movement in 2014 reflects growth in US sales, and changes in product and rebate programme mix, countered by the effect of faster collection from pharma benefit managers and authorities. The increase in inventory level partly reflects additional safety stock. Trade receivables and fixed assets have developed in line with Operating profit.<sup>63</sup>

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<sup>61</sup> See 2013 Annual Report, Novo Nordisk, [https://www.novonordisk.com/content/dam/Denmark/HQ/investors/irmaterial/annual\\_report/2014/20140203\\_Annual%20Report%202013\\_UK.pdf](https://www.novonordisk.com/content/dam/Denmark/HQ/investors/irmaterial/annual_report/2014/20140203_Annual%20Report%202013_UK.pdf), at 42.

<sup>62</sup> See 2014 Annual Report, Novo Nordisk, <https://www.novonordisk.com/content/dam/Denmark/HQ/Commons/documents/Novo-Nordisk-Annual-Report-2014.pdf>, at 8.

<sup>63</sup> *Id.* at 71.

163. On November 30, 2016, Novo issued a press release regarding AWP prices and actual profits that, among other things, stated:

News reports on drug prices have left the public with an impression that companies like ours realize all the profits from the “list price” increases we’ve made over the last decade. In other words, a list price increase by XX percent leads to an automatic XX percent profit for the drug maker. We believe that is misleading and here’s why: As the manufacturer, we do set the “list price” and have full accountability for those increases. However, after we set the list price, we negotiate with the companies that actually pay for the medicines, which we call payers. This is necessary in order for our medicines to stay on their preferred drug list or formulary. The price or profit we receive after rebates, fees and other price concessions we provide to the payer is the “net price.” The net price more closely reflects our actual profits.<sup>64</sup>

164. In 2009, Sanofi stated in its 20-F Form:

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products. In the United States, the Democrats, who currently hold majority in Congress and the presidency, have introduced a reform proposal designed to increase the government’s role in determining the price, reimbursement and the coverage levels for healthcare-related Expenses.<sup>65</sup>

165. In 2013, Sanofi stated in its 20-F Form:

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<sup>64</sup> See Press Release, [https://www.novonordisk-us.com/perspectives/our\\_perspectives.html](https://www.novonordisk-us.com/perspectives/our_perspectives.html).

<sup>65</sup> See 2009 20F Form, Sanofi, [https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/0000-2999/20F\\_2009-A.pdf](https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/0000-2999/20F_2009-A.pdf), at 8.

**The pricing and reimbursement of our products is increasingly affected by government and other third parties decisions and cost reduction initiatives.**

The commercial success of our existing products and our product candidates depends in part on the conditions under which our products are reimbursed. Our products continue to be subject to increasing price and reimbursement pressure due to, amongst others:

- price controls imposed by governments in many countries;
- removal of a number of drugs from government reimbursement schemes (for instance products determined to be less cost-effective than alternatives);
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- increase in cost containment policies related to health expenses in a context of economic slowdown; and
- the tendency of governments and private health care providers to favor generic pharmaceuticals.”

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products. For example, in the United States, the federal health care reform law is increasing the government’s role with respect to price, reimbursement and the coverage levels for healthcare services and products within the large government healthcare sector.<sup>66</sup>

166. In 2014, Sanofi stated in its 20-F Form:

**The pricing and reimbursement of our products is increasingly affected by government and other third parties decisions and cost reduction initiatives.**

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<sup>66</sup> See, 2013 20F Form, Sanofi [https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/fr/investisseurs/docs/0000-2999/20F\\_SANOFI\\_2013.pdf](https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/fr/investisseurs/docs/0000-2999/20F_SANOFI_2013.pdf), at 10.

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products; policies requiring the automatic substitution of generics or biosimilars could also be put in place.<sup>67</sup>

167. In 2011, Eli Lilly stated in its Annual Report:

We maintain special business groups to service wholesalers, pharmacy benefit managers, managed-care organizations, government and long-term care institutions, hospitals, and certain retail pharmacies. In response to competitive pressures, we have entered into arrangements with some of these organizations providing for discounts or rebates on Lilly products.<sup>68</sup>

168. In 2013, Eli Lilly stated in its Annual Report:

MCOs typically maintain formularies specifying which drugs are covered under their plans. Exclusion of a drug from a formulary can lead to its sharply reduced usage in the MCO patient population. Consequently, pharmaceutical companies compete aggressively to have their products included. Where possible, companies compete for inclusion based upon unique features of their products, such as greater efficacy, fewer side effects, or greater patient ease of use. A lower overall cost of therapy is also an important factor. Products that demonstrate fewer therapeutic advantages must compete for inclusion based primarily on price. We have been generally, although not always, successful in having our major products included on MCO formularies.<sup>69</sup>

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<sup>67</sup> See, 2014 20F Form, Sanofi, [https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/publications/38473\\_Sanofi\\_20-F\\_2014.pdf](https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/publications/38473_Sanofi_20-F_2014.pdf), at 10.

<sup>68</sup> See, 2011 Annual Report, Eli Lilly, <https://investor.lilly.com/static-files/96daf2d4-f329-42be-9069-fd158c2857ad>, at 3.

<sup>69</sup> See, 2013 Annual Report, Eli Lilly, <https://investor.lilly.com/static-files/8fc35b0c-76ef-4669-bb22-83cebd322f5e>, at B6.

169. In 2017, Eli Lilly spokesperson Julie Williams stated:

The amount the manufacturer receives after all discounts and rebates are applied is considerably less than the list price. For example, the net price for Humalog – our most commonly used insulin – increased by 4 percent over the five-year period of 2009 to 2014, which is a much smaller increase than what some consumers have experienced.<sup>70</sup>

170. Defendants made the above public statements to conceal their unlawful scheme to demand and receive kickbacks and to artificially fix, maintain and stabilize the price of the Insulin Drugs.

171. These statements were false and misleading because, *inter alia*, they failed to disclose to Plaintiffs and Class members that the increased prices that distributors were forced to pay for the Insulin Drugs were not a function of the need to preserve Defendants' actual profits or other appropriate market forces. These misleading statements concealed the kickback scheme.

172. In these public statements, Novo told investors and the public that it faced pressures to reduce prices and potential reduction in revenues, blaming government and private payers seeking to limit spending. Eli Lilly led investors and the public to believe competition for formulary listing depended on competition, efficacy and other attributes, not the amount of kickbacks paid. Sanofi let investors and the public to believe the pricing of its products was

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<sup>70</sup> See *The High Cost of Insulin (Plus a Plea to Lilly, Novo, and Sanofi)*, HEALTHLINE.COM, <http://www.healthline.com/diabetesmine/high-cost-insulin-and-plea-to-lilly#4>.

because of pressures on prices from government and third parties and generic competition, concealing the role kickbacks played in price increases.

173. Further, neither Defendants nor their co-conspirators told Plaintiffs nor other Class members that they were colluding and fixing prices.

174. Finally, PBMs are so secretive about their collection and distribution of drug company payments that, during an client audit, PBM Defendants, (i) require preapproval of the client's chosen auditor; (ii) restrict the number of drug company contracts that can be reviewed to a very limited number; (iii) restrict the number of claims and time period that can be reviewed; (iv) refuse to allow any drug company contract to be copied; (v) require a PBM representative to sit with every auditor that is reviewing a drug company contract; and (vi) refuse to allow any auditor to copy by hand the terms of any drug company contract, among other restrictions.

175. Plaintiffs and Class members could not have discovered the violations alleged herein earlier than late 2016, because Defendants acted in secret, concealed the nature of their unlawful conduct and acts in furtherance thereof, and fraudulently concealed their activities through various other means and methods designed to avoid detection. The conspiracy was by its nature self-concealing.

176. As a result of Defendants' fraudulent concealment of their conspiracy and illegal conduct, any applicable statute of limitations affecting the rights of action of Plaintiffs and Class members have been tolled.

**X. Class Action Allegations**

177. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), Plaintiffs bring this action on behalf of the following two direct purchaser classes:

- (1) all persons or entities that directly purchased NovoLog and/or Humalog from Defendants Eli Lilly and Company and Novo Nordisk Inc. in the U.S. and its territories, from January 1, 2009 through the present; and
- (2) all persons or entities that directly purchased Lantus and/or Levemir from Defendants Sanofi-Aventis U.S., LLC and Novo Nordisk Inc. in the U.S. and its territories, from January 1, 2009 through the present.

Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

178. Plaintiffs believe that there are dozens of Class members that are geographically dispersed throughout the U.S. As a result, joinder of all members of the respective Class is impracticable.

179. The Class members are readily identifiable from information and records maintained by Defendants.

180. Plaintiffs' claims are typical of the claims of the Class members. Plaintiffs' interests are not antagonistic to the claims of the other Class members,

and Plaintiffs possess no material conflicts with any other Class members that would make class certification inappropriate.

181. Plaintiffs and all Class members were damaged by the same wrongful conduct of Defendants. Plaintiffs and all Class members directly purchased one or more of the Insulin Drugs from Manufacturer Defendants, and therefore possess the requisite standing.

182. Plaintiffs will fairly and adequately protect and represent the interests of all Class members. Plaintiffs' interests are consistent with, and not antagonistic to, those of the Class members.

183. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular expertise pursuing class action litigation involving alleged antitrust violations.

184. Questions of law and fact common to Plaintiffs and Class members predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. As a result, determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

185. The predominant common legal and factual questions applicable to all Class members include, but are not limited to, the following:

- a. Whether Defendants engaged in a kickback scheme and thereby committed commercial bribery;

- b. Whether such conduct is a violation of Section 2(c) of the Robinson-Patman Act;
- c. The effect of such unlawful bribery on the prices of the Insulin Drugs in the U.S. during the Class Period;
- d. Whether Defendants participated in a contract, combination or conspiracy to fix, maintain and stabilize the price of the Insulin Drugs;
- e. The duration and extent of the alleged contract, combination or conspiracy;
- f. Whether such a contract, combination and conspiracy is *per se* unlawful under Section 1 of the Sherman Act;
- g. The effect of the contract, combination and conspiracy on the prices of Humalog, Novolog, Lantus, and Levemir in the U.S. during the Class Period;
- h. Whether Defendants engaged in mail and wire fraud in carrying out their unlawful kickback/price fixing scheme;
- i. Whether Defendants were engaged in one or more “enterprises” within the meaning of the federal RICO statute;
- j. Whether Defendants operated such RICO enterprise(s) through a pattern of racketeering activity including mail and wire fraud;
- k. Whether the alleged illegal conduct engaged in by Defendants comprised racketeering activity, in violation of federal RICO laws; and
- l. Whether, and to what extent, Defendants’ RICO violations caused injury to Plaintiffs and Class members in their business, trade or property.

186. Those common questions do not vary among the Class members. As a result, the Court and the jury may resolve those issues without reference to the individual circumstances of any member of the Class.

187. Class action treatment is a superior method for the fair and efficient adjudication of the claims asserted by all Class members. Such treatment will permit many similarly situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender.

188. The benefits of proceeding through the class mechanism, including providing all Class members a method for obtaining redress on claims that they could not practicably pursue individually, substantially outweigh potential difficulties in the management of this litigation as a class action.

189. Plaintiffs know of no special difficulty to be encountered in the management of this action that would preclude its maintenance as a class action.

## **XI. Claims for Relief**

### **Count One - Violation of the Robinson-Patman Act 15 U.S.C. § 13(c) Against All Defendants**

190. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

191. Section 2(c) of the Robinson-Patman Act provides that: “It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, of is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.” 15 U.S.C. § 13(c).

192. By engaging in the kickback and commercial bribery scheme described herein, Defendants have engaged in commercial bribery in violation of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c).

193. Manufacturer Defendants raised, fixed, and maintain the price for the Insulin Drugs based on the commercial bribery and kickback scheme described herein. PBM Defendants sought, and the Manufacturer Defendants paid, kickbacks, bribes and other unearned sums.

194. Pursuant to the kickback and commercial bribery scheme described above Defendants created illegal inducements that resulted in artificially inflated prices.

195. As a result of Defendants' unlawful conduct, Plaintiffs and Class members have purchased the Insulin Drugs at artificially inflated prices.

196. There is no appropriate or legitimate business justification for Defendants' anticompetitive conduct.

197. Defendants' unlawful conduct has resulted in competitive injury to Plaintiffs and the Class members by unduly restraining, hindering, suppressing and/or eliminating competition in the sale of commodities in interstate commerce.

198. As a direct and proximate result of Defendants' unlawful actions detailed herein, Plaintiffs have suffered substantial economic losses in the form of overcharges for the Insulin Drugs.

199. Plaintiffs and Class members are entitled to recover treble damages treble damages and costs of suit, including reasonable attorneys' fees pursuant to Section 4(a) of the Clayton Act, 15 U.S.C. § 15(a).

**Count Two - Violation of the Sherman Act  
15 U.S.C. § 1  
Against Manufacturer Defendants**

200. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

201. Manufacturer Defendants and their co-conspirators entered into, established and maintained a continuing contract, combination, or conspiracy in

unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

202. Manufacturer Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

203. Manufacturer Defendants' anticompetitive acts were intentional, were directed at the sales of the Insulin Drugs in the U.S. and had a substantial and foreseeable effect on interstate commerce by raising and fixing the Insulin Drug prices throughout the U.S.

204. In formulating and effectuating their combination or conspiracy, Manufacturer Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain and/or stabilize the prices of the Insulin Drugs including agreeing to coordinate and inflate the prices of the Insulin Drugs in a manner that deprived purchasers in the U.S. of price competition and providing pretextual justifications to purchasers and the public to explain any raises, maintenance or stabilization of the prices for the Insulin Drugs.

205. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the U.S.:

- a. Prices charged to, and paid by, Plaintiffs and Class members for the Insulin Drugs were artificially raised, fixed, maintained, or stabilized at supra-competitive levels;
- b. Plaintiffs and Class members were deprived of the benefits of free, open, and unrestricted competition in the sale of the Insulin Drugs in the relevant market; and
- c. Competition in establishing the prices paid for the Insulin Drugs was unlawfully restrained, suppressed, or eliminated.

206. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

207. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Manufacturer Defendants agreed with one another on the pricing of the Insulin Drugs in the U.S. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

208. Each Manufacturer Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

209. The conspiracy had its intended effect, as Manufacturer Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of the Insulin Drugs as described herein.

210. As a result of Manufacturer Defendants' unlawful conduct, Plaintiffs and Class members have been injured in their business and property in that they

have paid more for the Insulin Drugs than they otherwise would have paid in the absence of Manufacturer Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

**Count Three - Conspiracy to Violate the Sherman Act  
15 U.S.C. § 1  
Against All Defendants**

211. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

212. Defendants engaged in an overarching conspiracy to artificially fix, raise, maintain and/or stabilize the prices of the Insulin Drugs.

213. Defendants and their co-conspirators entered into, and engaged in, a contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

214. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

215. Defendants' anticompetitive acts were intentional, were directed at the sales of the Insulin Drugs in the U.S. and had a substantial and foreseeable effect on interstate commerce by raising and fixing the Insulin Drug prices throughout the U.S.

216. In formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain and/or stabilize the prices of the Insulin Drugs including agreeing to raise, fix, maintain, or stabilize the prices of the Insulin Drugs so that the PBM Defendants and the Manufacturer Defendants could benefit from higher coordinated prices in a manner that deprived purchasers in the U.S. of price competition and providing pretextual justifications to purchasers and the public to explain any raises, maintenance or stabilization of the prices for the Insulin Drugs.

217. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the U.S.:

- a. Prices charged to, and paid by, Plaintiffs and Class members for the Insulin Drugs were artificially raised, fixed, maintained, or stabilized at supra-competitive levels;
- b. Plaintiffs and Class members were deprived of the benefits of free, open, and unrestricted competition in the sale of the Insulin Drugs in markets; and
- c. Competition in establishing the prices paid for the Insulin Drugs was unlawfully restrained, suppressed, or eliminated.

218. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

219. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another on the pricing of the Insulin Drugs in the U.S. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

220. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

221. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of the Insulin Drugs as described herein.

222. As a result of Defendants' unlawful conduct, Plaintiffs and Class members have been injured in their business and property in that they have paid more for the Insulin Drugs than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

**Count Four - Violation of RICO, 18 U.S.C. § 1962(c)  
Against All Defendants**

223. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

224. For purposes of this claim, the RICO "enterprises" are associations-in-fact consisting of (a) one of the three PBM Defendants that administers insurance coverage of the Insulin Drugs, including its directors, employees, and agents, and

(b) one of the Manufacturer Defendants, including its directors, employees, and agents. These association-in-fact enterprises are collectively referred to herein as the “Insulin Pricing Enterprises.”

225. The Insulin Pricing Enterprises are as follows.

- **The Eli Lilly-PBM Insulin Pricing Enterprises.** The Eli Lilly-PBM Enterprises are three separate associations-in-fact, each consisting of a PBM Defendant that administers purchases of Eli Lilly’s Humalog (including its directors, employees, and agents), and Eli Lilly (including its directors, employees and agents): (1) the Eli Lilly-CVS association-in-fact enterprise; (2) the Eli Lilly-Express Scripts association-in-fact enterprise; and (3) the Eli Lilly-Optum association-in-fact enterprise.
- **The Novo-PBM Insulin Pricing Enterprises.** The Novo-PBM Enterprises are three separate associations-in-fact, each consisting of a PBM Defendant that administers purchases of Novo’s Novolog and Levemir (including its directors, employees, and agents), and Novo (including its directors, employees and agents): (1) the Novo-CVS association-in-fact enterprise; (2) the Novo-Express Scripts association-in-fact enterprise; and (3) the Novo-Optum association-in-fact enterprise.
- **The Sanofi-PBM Insulin Pricing Enterprises.** The Sanofi-PBM Enterprises are three separate associations-in-fact, each consisting of a PBM Defendant that administers purchases of Sanofi’s Lantus (including its directors, employees, and agents), and Sanofi (including its directors, employees and agents): (1) the Sanofi-CVS association-in-fact enterprise; (2) the Sanofi-Express Scripts association-in-fact enterprise; and (3) the Sanofi-Optum association-in-fact enterprise.

226. Each Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanging bribes and kickbacks — falsely

and misleading labeled as “rebates” or “fees” — for preferred formulary positions for Manufacturer Defendants’ particular Insulin Drug as treatments for type 1 and 2 diabetes.

227. Each Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between the particular Manufacturer Defendant and PBM Defendant.

228. As to each Enterprise, (i) there is a common communication network by which the particular Manufacturer Defendant and PBM Defendant respectively share information on a regular basis, and (ii) the particular Manufacturer Defendant and PBM Defendant function as continuing but separate units. At all relevant times, each Enterprise was operated and conducted by the particular Manufacturer Defendant and PBM Defendant for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme.

229. Each Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, promoting and recommending for purchase, and administering prescriptions for the Insulin Drugs and deriving secret profits from these activities.

230. These profits are greater than Defendants could obtain absent their fraudulent concealment of the true nature of substantial “rebates” and other fees from the Manufacturer Defendants to the PBM Defendants.

231. As part of and to accomplish the common purpose of the Insulin Pricing Enterprises, the Manufacturer Defendants systematically paid bribes and kickbacks — falsely labeled as rebates, administrative fees and/or other monies — to the PBM Defendants in exchange for exclusive and/or favorable formulary placement. The Manufacturer Defendants did so willfully, knowing that the sales of the Insulin Drugs were based on inflated list prices.

232. The Insulin Pricing Enterprises then reported the Manufacturer Defendants’ list price increases Plaintiffs and Class members, and to the respective PBM Defendant’s health benefit providers, while simultaneously concealing that the true reason for the price increases was to fund bribes and kickbacks to the PBM Defendants in exchange for formulary placement, and also to increase the dollar value of those bribes and kickbacks, and to increase profits to both the Manufacturer Defendants and to the PBM Defendants.

233. As outlined herein, the bribes and kickbacks paid by the Manufacturer Defendants to the PBM Defendants, which the PBM Defendants solicited and accepted, violated the federal anti-kickback statute.

234. The Manufacturer Defendants' list price increases were fraudulent, in that they were artificially inflated to fund the bribes and kickbacks, which the Insulin Pricing Enterprises concealed. The Insulin Pricing Enterprises also concealed the economic purpose of these list price increases to the Manufacturer Defendants and the PBM Defendants: the increases ultimately result in higher profits for the Manufacturer Defendants, enabling them to purchase formulary access without requiring significant price reductions; and they result in higher profits for the PBM Defendants, which are paid rebates, fees and other payments based on the Manufacturer Defendants' list prices increases and sales volume. In addition, the Manufacturer Defendants, as described above, realized significant increases in net profit through their substantial list prices increases, notwithstanding the increased payments (bribes and kickbacks) to PBM Defendants necessary to secure and maintain formulary placement of the Insulin Drugs and resulting insulin sales.

235. Each Insulin Pricing Enterprise also shares a common purpose of perpetuating the use of inflated Insulin Drug list prices. The Manufacturer Defendants required the inflated Insulin Drug list prices in part to fund the bribes and kickbacks to the PBM Defendants in exchange for favorable formulary positions. The PBM Defendants share this common purpose because the inflated

Insulin Drug list prices increase the value of the rebates, fees, and other monies they can keep, and thus increase their profits.

236. Formulary placement determines which drugs are covered and prescribed for purchase. Given that rebates and other fees to the PBM Defendants are determined and paid based in part on sales, the PBM Defendants provided formulary placement to the Insulin Drugs to ensure prescriptions and sales of those insulin products, maximizing their financial gains. As a result, the PBM Defendants have, in concert with the Manufacturer Defendants and through the respective Insulin Pricing Enterprises, engaged in hidden profit-making schemes, the PBM Defendants garnering rebates and other fees from the Manufacturer Defendants that the PBM Defendants, to a significant extent, keep, and do not share with or provide to their health benefit provider clients. The Manufacturer Defendants, meanwhile, unlawfully and fraudulently obtained sales, market share, and profits from the Insulin Drugs.

237. Each of the Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between each Manufacturer Defendant and each PBM Defendant that is an associate in the respective enterprise. As to each of the Insulin Pricing Enterprises, there is a common communication network by which each Manufacturer Defendant and each PBM shares information on a regular basis,

including information regarding insulin prices. As to each of the Insulin Pricing Enterprises, each Manufacturer Defendant and each PBM Defendant functioned as a continuing unit. At all relevant times, each of the Insulin Pricing Enterprises was operated for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme and its concealment.

238. At all relevant times, the Insulin Pricing Enterprises had an existence separate and distinct from that of its members. Eli Lilly, Novo, Sanofi, CVS, Express Scripts and Optum are distinct corporate entities. Further, each member of the respective RICO Enterprises has an existence separate and apart from the pattern of racketeering activities of the RICO Enterprise. Each Defendant carries on distinct businesses and operations. However, as alleged and described herein, each member of each Insulin Pricing Enterprise was essential to the operation of the scheme conducted through Insulin Pricing Enterprises.

239. The PBM Defendants, at all relevant times, have been knowing and willing participants in the conduct of the respective Insulin Pricing Enterprises, and have reaped large profits from that conduct. The PBM Defendants used their position to receive bribes and kickbacks for the Insulin Drugs from the Manufacturer Defendants and profit from the Manufacturer Defendants' inflated list prices. The PBM Defendants have represented to their respective health benefit provider clients and the public that the rebates lower drug costs when, in fact, as

the PBM Defendants are well aware, the inflated list prices required to fund the bribes and kickbacks to them in exchange for favorable formulary placement increased drug costs, including list prices and downstream reimbursement and cost-sharing obligations of health benefit providers and their members. In addition, as part of and to further the respective schemes, the PBM Defendants misrepresent and/or conceal from Plaintiffs and Class members, from health benefit provider clients, plan members, and the public the existence, amount and purpose of the rebates, fees and/or other monies the PBM Defendants are paid by the Manufacturer Defendants as well as the effect of the rebates, fees and/or other monies on the Insulin Drugs' list prices, and also publish, distribute and disseminate materials and information concerning the Insulin Drugs' list prices, net prices and the purpose of "rebates" and so-called "discounts" to conceal the Insulin Pricing Enterprises' schemes.

240. But for the Insulin Pricing Enterprises' common purpose of inflating the Manufacturer Defendants' list prices to fund the bribes and kickbacks, the list prices would not have artificially inflated or not to the same extent and the PBM Defendants would have had the incentive to disclose the fraudulent and collusive inflation of the Manufacturer Defendants' list prices, and would have used their control over the management and administration of their clients' formularies to penalize the Manufacturer Defendants' undue price increases. By concealing this

information, the PBM Defendants and the Manufacturer Defendants perpetuated the conduct of the Insulin Pricing Enterprises.

241. The PBM Defendants readily participated in the scheme so that they could continue to accept kickback from the Manufacturer Defendants that was calculated based on the Insulin Drugs' list price.

242. In order effectuate the scheme, each Manufacturer Defendant and each PBM Defendant met on a regular basis to discuss insulin prices, formulary position, rebates, administrative fees, other monies to the PBM Defendant, and coordination of all of the above.

243. Further, the common communication network between each PBM Defendant and each Manufacturer Defendant effectuated the purpose of implementing the list price inflation and rebate scheme and the exchange of financial rewards for the PBM activities that benefitted — and continue to benefit — the Manufacturer Defendants, as well as the PBM Defendants.

244. At all relevant times, each Manufacturer Defendant and each PBM Defendant knowingly, purposefully and willingly engaged and participated in the list price inflation and rebate scheme and the predicate acts of racketeering activity through each Insulin Pricing Enterprise, and reaped substantial profits from that scheme.

245. The Insulin Pricing Enterprises (Eli Lilly-CVS, Eli Lilly-Express Scripts, Eli Lilly-Optum, Novo-CVS, Novo-Express Scripts, Novo-Nordisk-Optum, Sanofi-CVS, Sanofi-Express Scripts, and Sanofi-Optum) knowingly made material misrepresentations and/or omissions to Plaintiffs and Class members as well as the PBM Defendants' health benefit provider clients, plan members, and to the general public in furtherance of the price inflation and rebate scheme. The material misrepresentations and omissions included:

- a. The reasons for the list price increases of the Insulin Drugs<sup>71</sup>;
- b. Whether PBM Defendants' "kickbacks" for formulary placement that were for payment for services actually rendered;
- c. The existence, purpose and amount of the bribes and kickbacks and other monies paid to the PBM Defendants;
- d. The effect of the rebates on Direct Purchaser Prices;
- e. The effect of the rebates and other monies on the PBM Defendants' development, management and administration of formularies;
- f. The extent to which Defendants negotiated rebates of the Insulin Drugs in good faith and for a proper purpose;
- g. Representations that the rebates were intended to benefit health benefit providers, plan members and/or the general public;
- h. Representations that the "preferred" formulary status of the Insulin

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<sup>71</sup> The Eli Lilly-PBM Insulin Pricing Enterprises made these misrepresentations with respect to Humalog. The Novo Nordisk-PBM Insulin Pricing Enterprises made these representations with respect to Novolog and Levemir. The Sanofi-PBM Insulin Pricing Enterprises made these misrepresentations with respect to Lantus.

Drugs reflected the drugs' safety, efficacy, or cost-effectiveness, as determined by the PBM Defendants' formulary committees;

- i. Omissions of fact that the PBM Defendants used their position regarding the development, management and administration for their own financial benefit and in contravention of the economic interests of their health benefit provider clients (and plan members);
- j. Omissions of fact and concealment of the fact that the Insulin Drugs would have been placed in "preferred" formulary positions absent the bribes; and
- k. By publishing artificially inflated prices.

246. Manufacturer Defendants alone could not have accomplished the purposes of the Insulin Pricing Enterprises without the PBM Defendants. For the Manufacturer Defendants to profit from the scheme, the PBM Defendants needed to convince health benefit providers to select their formularies, on which the Insulin Drugs were given favorable treatment. And the PBM Defendants did so through misrepresentations: they told clients, potential clients, and investors that they secured lower prices. Instead, Manufacturer Defendants inflated list prices and funded the bribes and kickbacks in exchange for favorable placement on the PBM Defendants' formularies, which resulted in increased drug costs. Without these misrepresentations, no Insulin Pricing Enterprise could have achieved its common purpose.

247. The impacts of the Insulin Pricing Enterprises are still in place as a result of Manufacturer Defendants' inflated list prices. As described herein, the

bribes and kickbacks are an essential part of the Insulin Pricing Enterprises and are embedded in ongoing the Insulin Drugs' prices. This conduct constitutes a threat of continued criminal activity.

248. The foregoing evidences that the Manufacturer Defendants and PBM Defendants were each willing participants in the Insulin Pricing Enterprises, had a common unlawful and fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, *i.e.*, to increase profits for both the Manufacturer Defendants and the PBM Defendants through price increases, bribes and kickbacks to the PBM Defendants, and continued formulary status without price reductions from the Manufacturer Defendants, preserving and increasing Manufacturer Defendants' profits.

#### **A. Conduct of the RICO Enterprises' Affairs**

249. During the Class Period, each of the Manufacturer Defendants has exerted control over each Insulin Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, each Manufacturer Defendant has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly, as follows:

- a. Controlling the list prices for the Insulin Drugs, which determine the amount of rebates, administrative fees, and other monies each of the PBM Defendants realizes in compensation in exchange for formulary placement;

- b. Controlling list prices for the Insulin Drugs and increases thereof that it publicly reports and purports to explain;
- c. Controlling the creation and distribution of marketing, sales, and other materials used to inform each of the PBM Defendants of the profit potential of the Insulin Drugs;
- d. Promoting the scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with the PBM Defendants;
- e. Providing bribes and kickbacks, falsely and misleadingly labeled as rebates or administrative fees, to induce the PBM Defendants to place the Insulin Drugs in a favorable position on the PBM's formulary;
- f. Intending that the PBM Defendants would (and did) distribute, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that rebates lowered drug costs for health benefit provider clients and their plan members; and
- g. Publishing and announcing collusive, artificially inflated list price increases and the reasons therefor but concealing that the increases were to fund the bribes and kickbacks to the PBM Defendants to secure favorable, preferred or exclusive formulary placement.

250. Further, during the Class Period, each PBM Defendant has exerted control over each Insulin Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, by, among other things as described herein:

- a. Soliciting and/or obtaining bribes and kickbacks (falsely labeled as rebates, so-called administrative fees, and/or other monies) in exchange for placing the Insulin Drugs in a favorable, preferred or exclusive position on the PBM's formularies;

- b. Misrepresenting and/or concealing from Plaintiffs, Class members, health benefit providers, plan members and the public the existence, amount, and purpose of the rebates, administrative fees and/or other monies from the Manufacturer Defendants;
- c. Misrepresenting and/or concealing from Plaintiffs, Class members, health benefit providers, plan members and the public the effect of the rebates, so-called administrative fees, and/or other monies from the Manufacturer Defendants on the Insulin Drug list prices; and
- d. Publishing, distributing and disseminating materials and information concerning the Insulin Drugs' list prices, net prices and/or the purpose of rebates and fees to perpetuate and conceal the scheme.

**B. Defendants' Pattern of Racketeering Activity**

251. Each Manufacturer Defendant and each of the PBM Defendants has conducted and participated in the affairs of the respective Insulin Pricing Enterprises through a pattern of racketeering activity under 18 U.S.C. § 1961, and committed the following violations outlined below knowingly and with the intent to advance the scheme.

252. Defendants' pattern of racketeering has involved thousands, if not hundreds of thousands, of racketeering acts, and has occurred over a number of years.

253. All of Defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purposes. The payments of bribes and kickbacks, misrepresentations and omissions, and separate uses of the U.S. mail

and/or interstate wires by Defendants and each Insulin Pricing Enterprise in connection with the illegal schemes were substantially related, had similar intended purposes, involved similar participants and methods of execution, and had similar results affecting similar victims. The racketeering activity constitutes a threat of continuing criminal activity.

254. Defendants have committed the following predicate acts, all constituting racketeering activity under 18 U.S.C. § 1961:

**1. Unlawful Bribery Under the Anti-Kickback Act**

255. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of the U.S. Specifically, in violation of 42 U.S.C. § 1320a-7b(b)(2) (the “Anti-Kickback Act”), each Manufacturer Defendant paid bribes to each of the PBM Defendants, which the PBM Defendants solicited and/or accepted, with the intention of purchasing, and in fact purchasing, formulary placement for the Insulin Drugs for which payment may be made in whole or in part under a Federal health care program.

256. No “safe harbor” applies, because “[r]ebates paid by drug companies to or through PBMs to buy formulary position are not reductions in price. In the

*Secretary's [of HHS] view, such a payment would not qualify as 'a discount or other reduction in price.'"* 82 F.R. 2340, at 2340 n.1 (emphasis added). *See also id.* at 2343 ("To the extent those rebates are paid to or through PBMs to buy formulary position, such payments would not be protected by the discount statutory exemption.").

257. The Anti-Kickback Act is a criminal prohibition against payments made purposefully to induce or reward the referral or generation of federal health care business. The Anti-Kickback Act criminalizes a drug company's offer or payment of anything of value in return for a PBM's placing that manufacturer's drug in a favorable formulary position with respect to, in whole or part, a federal health care program. This includes a drug manufacturer's offer or payment to a PBM respecting private, nonfederal business that implicitly or explicitly requires that the PBM place the manufacturer's drug in a favorable position with respect to a federal health care program. The Anti-Kickback Act extends not just to a drug manufacturer's payment, but also to the solicitation or acceptance of remuneration by PBMs.

258. The OIG and the Secretary of HHS have long warned that "[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized." 68 F.R. 23731, at 23736 (2003).

259. The OIG and the Secretary of HHS have also stated that PBMs are not, and have never been, “buyers” within the meaning of the Anti-Kickback Act’s “safe harbor” for “discounts.” 82 F.R. 2340, 2343 n.36 (2019) (“the payments manufacturers retrospectively make to PBMs under rebate agreements would not constitute discounts or other reductions in price to the extent such payments are retained by the PBM and not passed through to any buyer”).

260. The purported rebates and fees afforded by the Defendant PBMs to the Manufacturer Defendants do not fall within the safe harbor provision because they are not pure “rebates” or fees alone. As stated, they are accompanied by the quid pro quo of getting preferred formulary treatment. Additionally, these supposed “rebates” do not reduce the Manufacturer Defendants’ selling prices as they increased prices to make up for an increased “rebate.”

## **2. Mail and Wire Fraud**

261. During the Class Period, each of the Insulin Pricing Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, promotion, recommendation for purchase, and/or administration of prescriptions of the Insulin Drugs; the setting of the prices of the Insulin Drugs and price increase announcements in connection therewith; the negotiation of formulary placement, rebate, and other contracts; the transmission and/or receipt of sales and marketing literature; and/or the transmission

and/or receipt of invoices, statements, and payments related to the purchase, use and/or administration of the Insulin Drugs. During the Class Period, the Insulin Pricing Enterprises participated in the sale, promotion, recommendation for purchase, and administration of prescriptions for the Insulin Drugs throughout the U.S.

262. During the Class Period, Defendants' illegal conduct and wrongful practices in furtherance of the Insulin Pricing Enterprises were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

263. The nature and pervasiveness of the Defendants' scheme, which was concertedly orchestrated out of the respective corporate headquarters of the Manufacturer Defendants and the PBM Defendants, necessarily required those Manufacturer Defendants' headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the headquarters of the PBM Defendants, and vice versa.

264. Most of the precise dates of Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts as outlined herein) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful

operation of the bribery and kickback scheme alleged herein depended upon secrecy. Defendants took deliberate steps to conceal their wrongdoing. Plaintiffs can nevertheless generally describe the occasions on which the RICO predicate acts of unlawful payment of bribes and kickbacks, mail fraud, and wire fraud occurred, and how those acts were in furtherance of the list price inflation and rebate bribery and kickback scheme.

265. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the scheme involved thousands of communications throughout the Class Period including, *inter alia*:

- a. Publication of artificially inflated prices and publication of marketing materials about the collusively set artificial list prices for the Insulin Drugs, which Manufacturer Defendants sent to PBM Defendants and others located across the country;
- b. Written and oral representations about the Insulin Drug list prices that Manufacturer Defendants made at least annually and, in many cases, several times during a single year;
- c. Thousands of written and oral communications discussing, negotiating, conditioning, and confirming the placement of the Insulin Drugs on a particular PBM Defendant's formulary;
- d. Written and oral representations to conceal the true reasons for the Insulin Drugs' list price increases and to conceal the scheme;
- e. Written communications, including checks, wires and/or other payment mechanisms, relating to rebates, bribes, kickbacks, or other financial inducements paid by each of the Manufacturer Defendants to each of the PBM Defendants to induce them to place the Insulin Drugs on the PBM Defendants' formularies in a favorable position;

- f. Written and oral communications with U.S. government agencies and health benefit providers that fraudulently misrepresented the reasons for list price increases, or that were intended to deter investigations into the true nature of the list price increases or to forestall changes to reimbursement based on something other than list prices;
- g. Written and oral communications with direct purchasers, health benefit providers, and patients concerning list prices and the reasons for increases thereof;
- h. Written and oral communications by the PBM Defendants and/or the Manufacturer Defendants with health benefit providers, and patients concerning list prices and/or the reasons for increases thereof;
- i. Transmission of list prices using the mails or wires from Manufacturer Defendants to Plaintiffs, Class members, and third parties;
- j. Sending invoices and requests for payment to Plaintiff and Class members using the mails and wires;
- k. Receipts and payments of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities, constituting the wrongful proceeds of the list price inflation and bribery scheme, including Plaintiffs and Class members; and
- l. In addition to the RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their own various local headquarters or divisions, in furtherance of the list price inflation and bribery scheme.

266. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B),

Defendants have, in violation of 18 U.S.C. § 1341, used the U.S. mails in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false

or fraudulent pretenses, representations, or promises. Specifically, as outlined above, each Insulin Drug has been promoted through the mails, thereby announcing to health benefits providers and Plaintiffs and Class members each Manufacturer Defendant's artificially inflated list price increases, but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Manufacturer Defendant's bribes and kickbacks to each of the PBM Defendants to secure formulary placement. Moreover, Defendants have falsely and misleadingly called the bribes and kickbacks to the PBM Defendants "rebates" — which have been publicly represented as lowering drug costs — when they are, in fact, bribes and kickbacks for formulary placement, which enabled each Manufacturer Defendant to sell insulin at inflated prices.

267. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails in furtherance of their schemes.

268. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1343, transmitted or caused to be transmitted by means of wire, radio, or television communication in interstate commerce, in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises. Specifically, as outlined above, each of the Insulin Drugs has been promoted

through electronic means, thereby announcing to Plaintiffs and Class members, health benefit providers, patients and the public its collusive and artificially high list price increases, but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Manufacturer Defendant's bribes and kickbacks to each of the PBM Defendants to secure formulary placement. Moreover, Defendants have falsely and misleadingly called the bribes and kickbacks to the PBM Defendants "rebates" — which have been publicly represented as lowering drug costs — when they are, in fact, bribes and kickbacks for formulary placement, which enabled each Manufacturer Defendant to sell the Insulin Drugs at inflated prices.

269. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of interstate wires in furtherance of their schemes.

### **C. Harm Caused by the Defendants' Bribery, Kickback and Fraud Scheme**

270. Defendants' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and Class members to be injured in their business or property by overpaying for the Insulin Drugs. Plaintiffs and the Class directly purchased the Insulin Drugs from the Manufacturer Defendants, and thus were directly and immediately harmed Defendants' schemes. Each of the Manufacturer Defendants and each of the PBM Defendants intended

and foresaw that Plaintiffs and Class members would, by paying artificially inflated list prices for the Insulin Drugs, pay substantial overcharges due to Defendants' pattern of racketeering activity.

271. During the Class Period, Manufacturer Defendants paid bribes and kickbacks to the PBM Defendants in exchange for preferred formulary placement in order to maintain and/or increase sales and profits. To fund these bribes and kickbacks, with the knowledge and agreement of the PBM Defendants the Manufacturer Defendants colluded to increase the list prices of the Insulin Drugs, which causes the prices Plaintiffs and Class members paid to be artificially high.

272. Though the PBM Defendants could have used their control over the development, management, and administration of the formularies and prescription drug programs that their health benefit providers relied upon to drive down the prices for insulin by forcing Manufacturer Defendants to lower their list prices, the PBM Defendants instead leveraged their position to obtain Manufacturer Defendants' bribes and kickbacks for their own financial benefit and contrary to the economic interests of their health benefit provider clients and plan members.

273. Rather than lower their prices to gain market share via formulary inclusion, Manufacturer Defendants instead engaged in a scheme with the PBM Defendants to corrupt the supply chain by artificially inflating list prices in exchange for preferred formulary placement, shifting the cost of the bribes and

kickbacks to direct purchasers of the Insulin Drugs such as Plaintiffs and the Class and sharing those financial benefits with the PBM Defendants.

274. Plaintiffs and Class members are the only purchasers of the Insulin Drugs directly from Manufacturer Defendants and were directly harmed by Manufacturer Defendants' price inflation and rebate schemes with the PBM Defendants.

275. Absent the payment of bribes and kickbacks, and their achievement through the Insulin Drugs' list price increases, Manufacturer Defendants would have been forced to compete for preferred formulary placement through lower prices, as they would in a legitimate market. As the gatekeepers in the supply chain the Defendant PBMs could and would have used formulary placement (or exclusion) to penalize manufacturers who raised prices as Manufacturer Defendants did here, rather than perversely rewarding manufacturers who raised prices and inducing them to do so with favorable formulary placement.

276. But for the payment of bribes and kickbacks, and their achievement through list price increases, the Insulin Drugs would have had a lower list price, and Plaintiffs and Class members would have paid less for the Insulin Drugs. Plaintiffs and Class members have overpaid hundreds of millions of dollars for the Insulin Drugs purchased directly from Manufacturer Defendants based on inflated list prices.

277. Defendants' racketeering activity directly and proximately caused Plaintiffs' and Class members' injuries because Plaintiffs and the Class members were and are the initial and only direct purchasers of the Insulin Drugs from the Manufacturer Defendants. Further, given that Plaintiffs and the Class members were and are the most direct and immediate victims of the unlawful and fraudulent schemes, Plaintiffs and the Class members are best situated to vindicate the law and seek recovery for the economic harm caused by Defendants based on the substantial overcharges for the Insulin Drugs, which only Plaintiffs and the Class members paid.

278. By virtue of these violations of 18 U.S.C. § 1962(c), pursuant to 18 U.S.C. § 1964(c), Defendants are, respectively, jointly and severally liable to Plaintiffs and Class members for three times the overcharges that Plaintiffs and Class members have paid, plus the costs of bringing this suit, including reasonable attorneys' fees.

**Count Five - Violation of RICO, 18 U.S.C. § 1962(d)  
By Conspiring to Violate 18 U.S.C. § 1962(c)  
Against All Defendants**

279. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

280. Section 1962(d) of RICO provides that it “shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section.”

281. Each Manufacturer Defendant and each of the PBM Defendants has violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of the respective conspiracies has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Manufacturer-PBM Insulin Pricing Enterprises described previously through a pattern of racketeering activity.

282. As set forth in detail above, Defendants have engaged in numerous overt and predicate unlawful and fraudulent acts, constituting a pattern of racketeering activity, in furtherance of the conspiracy. Defendants intended to engage in the schemes resulting in Plaintiffs and the Class members paying substantial overcharges for the Insulin Drugs. Defendants knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of those acts to further the schemes outlined herein.

283. The nature of the Defendants’ acts, material misrepresentations and omissions in furtherance of the conspiracy, as set forth in detail above, gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were

aware that their ongoing unlawful and fraudulent acts have been and are part of an overall pattern of racketeering activity.

284. Defendants have engaged (and continue to engage) in the commission of overt acts in furtherance of the Manufacturer-PBM Insulin Pricing Enterprise schemes, including the following unlawful racketeering predicate acts (as outlined in detail above):

- a. Multiple instances of unlawful bribery and kickbacks in violation of 18 U.S.C. § 1952 and various federal laws comprising racketeering activity under 18 U.S.C. § 1961;
- b. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341; and
- c. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343.

285. Defendants' violations of the above federal laws and the effects thereof outlined in detail above are continuing and will continue. As a direct and proximate result of these violations, Plaintiffs and Class members have been injured in their business and property; Plaintiffs and Class members have made hundreds of millions of dollars in overpayments for the Insulin Drugs purchased directly from the Manufacturer Defendants that they would not have paid but for the Defendants' conspiracies to violate 18 U.S.C. § 1962(c).

286. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are, respectively, jointly and severally liable to Plaintiffs and the Class for three times

the damages Plaintiffs and the Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

### **XII. Prayer for Relief**

WHEREFORE, Plaintiffs and the Class members pray for relief as set forth below:

- A. Certification of the Class pursuant to Federal Rule of Civil Procedure 23, appointment of Plaintiffs as representatives, and appointment of Plaintiffs' counsel as Class counsel;
- B. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiffs and the Class members defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;
- C. Pre-judgment and post-judgment interest at the highest legal rate;
- D. The costs of this suit, including reasonable attorneys' fees; and
- E. Such other and further relief as the Court deems just and proper.

### **XIII. Jury Demand**

Plaintiffs, on behalf of themselves and all others similarly situated, hereby request a jury trial, pursuant to Federal Rule of Civil Procedure 38, on all claims so triable.

Dated: November 6, 2020.

Respectfully submitted,

*/s/ Matthew F. Gately*

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